

CCNs published January 1, 2018 - May 25, 2020

Change Control Notification - Density Gradient Media

Global Notifications

Published on: 05/15/2020	Notification on Legal Entity changes
Published on: 05/14/2020	Final reminder for Notification on re-designed web page for Change Notifications and Regulatory Support Documentation
Published on: 05/11/2020	Reminder for Notification on re-designed web page for Change Notifications and Regulatory Support Documentation.
Published on: 04/27/2020	Update on Notification on re-designed web page for Change Notifications and Regulatory Support Documentation.
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Published on: 09/06/2019	Notification on Legal Entity changes - Correction_CCN
Published on: 08/30/2019	Notification on Legal Entity changes
Published on: 07/15/2019	Pre-notification on change of company name
Published on: 07/08/2019	Pre-notification new Regulatory Support web page
Published on: 07/06/2018	Update of GE Healthcare Life Sciences' Change Control Standard
Published on: 03/05/2018	Update of GE Healthcare Life Sciences' Change Control Standard

Percoll

Published on: 01/10/2020	Updated labels for products Percoll and Percoll PLUS
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Percoll PLUS

Published on: 01/10/2020	Updated labels for products Percoll and Percoll PLUS
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Change Control Notification - Synthesis of oligonucleotides

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Published on: 07/06/2018	Update of GE Healthcare Life Sciences' Change Control Standard
Published on: 03/05/2018	Update of GE Healthcare Life Sciences' Change Control Standard

OligoPilot 400

Published on: 06/17/2019	New valve design in OligoPilot 400_CCN 14-Jun-2019
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Change Control Notification - Biacore

Global Notifications

Published on: 05/15/2020	Notification on Legal Entity changes
Published on: 05/11/2020	Reminderfor Notification on re-designed web page for Cange Notifications and Regulatory Support Documentation.
Published on: 04/27/2020	Update on Notification on re-designed web page for Cange Notifications and Regulatory Support Documentation.
Published on: 04/08/2020	Administrative update of standard for the change control process for designated Biacore products
Published on: 04/01/2020	Notification on change of company name
Published on: 03/20/2020	Notification on Legal Entity changes
Published on: 12/20/2019	Correction to notification regarding Legal entity changes for China
Published on: 11/29/2019	Notification on Legal Entity changes for Russia, China and India
Published on: 11/28/2019	IFUs removed from Biacore packaging_CCN 28Nov2019
Published on: 10/14/2019	Notification on Company Brand name and Legal Entity changes
Published on: 10/01/2019	Update to Pre-notification on new RS web page published 08 July 2019
Published on: 09/06/2019	Notification on Legal Entity changes - Correction
Published on: 08/30/2019	Notification on Legal Entity changes

Published on: 07/15/2019	Pre-notification on change of company name
Published on: 07/08/2019	Pre-notification new Regulatory Support web page
Published on: 05/08/2018	Update of standard for the change control process for designated Biacore products TW 357526

Amine Coupling Kit

Published on: 05/06/2020	Changed labels for Biacore kits_CCN 06-May-2020
Published on: 01/16/2020	Change of supplier of Biacore amine coupling kits_CCN 16-Jan-2020

Amine Coupling Kit, type 2

Published on: 05/06/2020	Changed labels for Biacore kits_CCN 06-May-2020
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Biacore 3000

Published on: 12/11/2018	Discontinuation of Biacore 3000 and Biacore 4000_CCN 11Dec2018
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Biacore 4000

Published on: 12/11/2018	Discontinuation of Biacore 3000 and Biacore 4000_CCN 11Dec2018
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Biacore C

Published on: 12/20/2019	Discontinuation of Biacore C_CCN 20-Dec-2019
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Biacore T 200

Published on: 12/05/2019	Biacore T200 v 3.2 Software Note_CCN 05-Dec-2019
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Biotin CAPture Kit

Published on: 05/04/2018	New dextran lot for Biacore sensor chips_CCN 04May2018
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Biotin CAPture Kit_Series S

Published on: 05/04/2018	New dextran lot for Biacore sensor chips_CCN 04May2018
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HBS-EP+ 10X

Published on: 05/23/2019	New supplier of Biacore running buffers_CCN 22May2019
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HBS-N 10X

Published on: 05/23/2019	New supplier of Biacore running buffers_CCN 22May2019
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HBS-P+ 10X

Published on: 05/23/2019	New supplier of Biacore running buffers_CCN 22May2019
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Mouse Antibody Capture Kit

Published on: 04/26/2018 Updated analytical specification for Mouse Antibody Capture Kit

PBS 10X

Published on: 05/23/2019 New supplier of Biacore running buffers_CCN 22May2019

Qflex kit Biotin

Published on: 05/04/2018 New dextran lot for Biacore sensor chips_CCN 04May2018

Published on: 03/05/2018 Change in manufacturing of Biacore Sensor Chip

Qflex kit Folic Acid

Published on: 05/04/2018 New dextran lot for Biacore sensor chips_CCN 04May2018

Published on: 03/05/2018 Change in manufacturing of Biacore Sensor Chip

Qflex kit Pantothenic Acid PI

Published on: 05/04/2018 New dextran lot for Biacore sensor chips_CCN 04May2018

Published on: 04/20/2018 Change in manufacturing of Biacore Sensor Chip

Qflex kit Vitamin B12 PI

Published on: 05/04/2018 New dextran lot for Biacore sensor chips_CCN 04May2018

Published on: 04/20/2018 Change in manufacturing of Biacore Sensor Chip

Sensor Chip CM4

Published on: 05/04/2018 New dextran lot for Biacore sensor chips_CCN 04May2018

Sensor Chip CM5

Published on: 05/04/2018 New dextran lot for Biacore sensor chips_CCN 04May2018

Sensor Chip CM7

Published on: 05/04/2018 New dextran lot for Biacore sensor chips_CCN 04May2018

Sensor Chip NTA

Published on: 10/01/2019 Change of NTA raw material in Biacore sensor chips_CCN 01-Oct-2019

Published on: 07/10/2019 Change Control Notification about change of NTA raw material in Biacore sensor chips_10-Jul-2019

Published on: 05/04/2018 New dextran lot for Biacore sensor chips_CCN 04May2018

Sensor Chip Protein A

Published on: 05/04/2018 New dextran lot for Biacore sensor chips_CCN 04May2018

Sensor Chip Protein G

Published on: 05/04/2018 New dextran lot for Biacore sensor chips_CCN 04May2018

Sensor Chip Protein L

Published on: 05/04/2018 New dextran lot for Biacore sensor chips_CCN 04May2018

Series S Sensor Chip CM4

Published on: 05/04/2018 New dextran lot for Biacore sensor chips_CCN 04May2018

Series S Sensor Chip CM5

Published on: 05/04/2018 New dextran lot for Biacore sensor chips_CCN 04May2018

Series S Sensor Chip CM7

Published on: 05/04/2018 New dextran lot for Biacore sensor chips_CCN 04May2018

Series S Sensor Chip NTA

Published on: 10/01/2019 Change of NTA raw material in Biacore sensor chips_CCN 01-Oct-2019
Published on: 07/10/2019 Change Control Notification about change of NTA raw material in Biacore sensor chips_10-Jul-2019
Published on: 05/04/2018 New dextran lot for Biacore sensor chips_CCN 04May2018

Series S Sensor Chip Protein A

Published on: 05/04/2018 New dextran lot for Biacore sensor chips_CCN 04May2018

Series S Sensor Chip Protein G

Published on: 05/04/2018 New dextran lot for Biacore sensor chips_CCN 04May2018

Series S Sensor Chip Protein L

Published on: 05/04/2018 New dextran lot for Biacore sensor chips_CCN 04May2018

Thiol Coupling Kit

Published on: 05/06/2020 Changed labels for Biacore kits_CCN 06-May-2020

Change Control Notification - Bioprocess Hardware

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Published on: 07/06/2018	Update of GE Healthcare Life Sciences' Change Control Standard
Published on: 03/05/2018	Update of GE Healthcare Life Sciences' Change Control Standard

Axichrom

Published on: 09/09/2019	Removal of bottom fasteners on AxiChrom 300-1600_CCN 09Sep2019
Published on: 04/26/2019	Changed material in pumps in Chromaflow Packing Stations and Media Handling Unit_CCN 26-Apr-2019
Published on: 01/24/2019	Change of thread inserts on AxiChrom 300-1000 distributor plates_CCN 23Jan2019
Published on: 01/11/2019	Changed color of AxiChrom O-rings_CCN 11Jan2019
Published on: 10/24/2018	Change of feet for AxiChrom columns_CCN 24Oct2018
Published on: 06/14/2018	Change O-ring dimensions on AxiChrom™ 800 and AxiChrom 1000 columns
Published on: 05/18/2018	Change of supplier of O-rings for AxiChrom 300-1000_CCN 18May2018
Published on: 03/02/2018	Change of supplier of O-rings for AxiChrom 300-1000_CCN 02Mar2018
Published on: 01/31/2018	Design update scraper AxiChrom 800_CCN 31Jan2018

ÄKTA flux

Published on: 08/13/2019	Changed accessory for ÄKTA flux s_CCN 13-Aug-2019
Published on: 07/04/2018	Changed accessory for ÄKTA flux s_CCN 04Jul2018
Published on: 01/15/2018	Change of air-filter for ÄKTA flux 6_CCN 15Jan2018

ÄKTA ready

Published on: 08/13/2019	New product codes for pH electrodes_CCN v2_13Aug2019
Published on: 04/18/2019	New product codes for pH electrodes_CCN 18-Apr-2019
Published on: 03/07/2019	New power supplies for ÄKTApocess and ÄKTAreedy_CCN 07Mar2019
Published on: 07/06/2018	New circuit breaker in ÄKTApocess and ÄKTA ready_CCN 06Jul2018

ÄKTAcrossflow

Published on: 08/13/2019	New product codes for pH electrodes_CCN v2_13Aug2019
Published on: 04/18/2019	New product codes for pH electrodes_CCN 18-Apr-2019
Published on: 05/25/2018	Change of valve membrane in ÄKTAcrossflow_CCN 25May2018

ÄKTApilot

Published on: 08/13/2019	New product codes for pH electrodes_CCN v2_13Aug2019
Published on: 04/18/2019	New product codes for pH electrodes_CCN 18-Apr-2019
Published on: 06/21/2018	Discontinuation of ÄKTA pilot_CCN 21Jun2018
Published on: 02/28/2018	Redesigned test kits used for UV monitor verification

ÄKTApocess

Published on: 02/18/2020	Computer update for ÄKTApocess and UniFlux_CCN 18-Feb-2020
Published on: 08/13/2019	New product codes for pH electrodes_CCN v2_13Aug2019
Published on: 04/18/2019	New product codes for pH electrodes_CCN 18-Apr-2019
Published on: 03/07/2019	New power supplies for ÄKTApocess and ÄKTAreedy_CCN 07Mar2019
Published on: 02/12/2019	Change of O-rings in air traps for ÄKTApocess_CCN 12Feb2019
Published on: 09/26/2018	Change of PM record for ÄKTApocess_CCN 26Sep2018
Published on: 07/06/2018	New circuit breaker in ÄKTApocess and ÄKTA ready_CCN 06Jul2018
Published on: 07/05/2018	Change of ÄKTApocess PM record_CCN 05Jul2018
Published on: 02/28/2018	Redesigned test kits used for UV monitor verification

BioProcess System

Published on: 02/28/2018	Redesigned test kits used for UV monitor verification
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BPG

Published on: 02/11/2020	Changes for BPG 140 and 200_CCN 11-Feb-2020
Published on: 12/20/2018	New screws and springs for BPG columns_CCN 20Dec2018
Published on: 01/17/2018	Change of BPG column Packing Devices_CCN 17Jan2018

Chromaflow (300-1000 standard)

Published on: 04/26/2019	Changed material in pumps in Chromaflow Packing Stations and Media Handling Unit_CCN 26-Apr-2019
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Chromaflow (Pack 50, 100)

Published on: 04/26/2019 Changed material in pumps in Chromaflow Packing Stations and Media Handling Unit_CCN 26-Apr-2019

FineLINE

Published on: 11/23/2018 Change of wheel for FineLINE 350 column_CCN 23Nov2018

UniFlux (10,30,120)

Published on: 02/18/2020 Computer update for ÄKTApocess and UniFlux_CCN 18-Feb-2020
Published on: 08/13/2019 New product codes for pH electrodes_CCN v2_13Aug2019
Published on: 04/18/2019 New product codes for pH electrodes_CCN 18-Apr-2019
Published on: 01/17/2019 Change of temperature transmitter in Xcellerex XDM mixing systems
Published on: 07/05/2018 Change of UniFlux PM record_CCN 05Jul2018
Published on: 04/11/2018 New pump in UniFlux 10 Corrected spare part info_CCN_11Apr2018
Published on: 04/10/2018 New pump in UniFlux 10_CCN_10Apr2018

Change Control Notification - BioProcess Software

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Published on: 07/06/2018 Update of GE Healthcare Life Sciences' Change Control Standard

Published on: 03/05/2018 Update of GE Healthcare Life Sciences' Change Control Standard

FlexFactory Automation information letter

Published on: 03/20/2020 FlexFactory Automation 2.1.0 Information Letter

Published on: 05/02/2018 FlexFactory Automation 2.0.0 Information Letter

UNICORN information letter

Published on: 03/24/2020 License server vulnerability affecting UNICORN™ software_24-Mar-2020

Published on: 01/31/2020 UNICORN 7.5 Information Letter_CCN 31-Jan-2020

Published on: 10/04/2019 UNICORN cyber security Recommended action_04-Oct-2019

Published on: 07/08/2019 Change Control Notification with UNICORN 7.4 Software Information Letter 08Jul2019

Published on: 03/23/2018 CCN UNICORN 7.3 Software Information Letter_23Mar2018

Published on: 01/09/2018 CCN UNICORN 7.2 Information Letter

UNICORN Software change description

Published on: 03/24/2020 License server vulnerability affecting UNICORN™ software_24-Mar-2020

Published on: 01/31/2020 UNICORN 7.5 Software Change Description_CCN 31-Jan-2020

Published on: 10/04/2019 UNICORN cyber security Recommended action_04-Oct-2019

Published on: 07/08/2019 Change Control Notification with UNICORN Software Change Description_08Jul2019

Published on: 03/23/2018 CCN UNICORN Software Change Description_23Mar2018

Published on: 01/09/2018 CCN UNICORN 7.2 Software Change Description

Change Control Notification - Cell and gene therapy:

Cell culture media and reagents

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Change Control Notification - Cell and gene therapy: Sepax, Sefia, Smart-Max, ViaFreeze, ViaThaw, Xuri

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Published on: 04/01/2020	Notification on change of company name
Published on: 03/26/2020	191227MXWS-02 - UPDATE Addition of supplier manufacturing sites for C-Flex® TPE tubing _Xu
Published on: 03/20/2020	Notification on Legal Entity changes
Published on: 12/27/2019	191227MXWS-01 - Addition of supplier manufacturing sites for C-Flex® TPE tubing _Xu
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Published on: 07/06/2018	Update of GE Healthcare Life Sciences' Change Control Standard

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Sefia S-2000

Published on: 05/12/2020	Correction to FlexCell and PremierCell Sefia S-2000 applications Softwares and BPAS software update availability published 22 April 2020
Published on: 04/24/2020	Impact on Cell & Gene Therapy non-medical device products produced in Eysins, Switzerland since GE Healthcare Life Sciences (Biopharma business) is
Published on: 04/22/2020	FlexCell and PremierCell Sefia S-2000 applications Softwares and BPAS software update availability.
Published on: 08/30/2019	Sepax and Sefia instruments, component change

Published on: 08/08/2019	Sefia S-2000 software operating system update
Published on: 07/24/2019	Pre-notification regarding Sepax and Sefia machines - component machine change
Published on: 08/08/2019	Sefia S-2000 software operating system update
Published on: 07/16/2019	Pre-notification regarding Microsoft Windows Operating System Security Vulnerability

Sefia: CT-300.1 box of 8 Kits Sterile

Published on: 04/24/2020	Impact on Cell & Gene Therapy non-medical device products produced in Eysins, Switzerland since GE Healthcare Life Sciences (Biopharma business) is
Published on: 10/03/2019	Update to Pre-notification for Sepax and Sefia, material change in component
Published on: 05/13/2019	Pre-notification for Sepax and Sefia, material change in component
Published on: 02/08/2019	Change in manufacturing of component for Sepax™ and Sefia™
Published on: 11/23/2018	Change in manufacturing and material of construction for Sefia Cell Processing Kits.

Sefia: CT-800.1 - Box of 8 Units

Published on: 04/24/2020	Impact on Cell & Gene Therapy non-medical device products produced in Eysins, Switzerland since GE Healthcare Life Sciences (Biopharma business) is
Published on: 10/03/2019	Update to Pre-notification for Sepax and Sefia, material change in component
Published on: 05/13/2019	Pre-notification for Sepax and Sefia, material change in component
Published on: 02/08/2019	Change in manufacturing of component for Sepax™ and Sefia™
Published on: 11/23/2018	Change in manufacturing and material of construction for Sefia Cell Processing Kits.

Sefia: FlexCell Sefia protocol software

Published on: 05/12/2020	Correction to FlexCell and PremierCell Sefia S-2000 applications Softwares and BPAS software update availability published 22 April 2020
Published on: 04/24/2020	Impact on Cell & Gene Therapy non-medical device products produced in Eysins, Switzerland since GE Healthcare Life Sciences (Biopharma business) is
Published on: 04/22/2020	FlexCell and PremierCell Sefia S-2000 applications Softwares and BPAS software update availability.

Sefia: PremierCell Sefia protocol software

Published on: 05/12/2020	Correction to FlexCell and PremierCell Sefia S-2000 applications Softwares and BPAS software update availability published 22 April 2020
Published on: 04/24/2020	Impact on Cell & Gene Therapy non-medical device products produced in Eysins, Switzerland since GE Healthcare Life Sciences (Biopharma business) is
Published on: 04/22/2020	FlexCell and PremierCell Sefia S-2000 applications Softwares and BPAS software update availability.

Sefia: PremierCell Sefia protocol software

Published on: 02/07/2020	Sepax TeamViewer software update
Published on: 11/20/2019	New version of Sepax software operating system
Published on: 08/30/2019	Sepax and Sefia instruments, component change
Published on: 07/24/2019	Pre-notification regarding Sepax and Sefia machines - component machine change
Published on: 07/16/2019	Pre-notification regarding Microsoft Windows Operating System Security Vulnerability

Sepax 2 S-100

Published on: 02/07/2020	Sepax TeamViewer software update
Published on: 11/20/2019	New version of Sepax software operating system
Published on: 08/30/2019	Sepax and Sefia instruments, component change
Published on: 07/24/2019	Pre-notification regarding Sepax and Sefia machines - component machine change
Published on: 07/16/2019	Pre-notification regarding Microsoft Windows Operating System Security Vulnerability

Sepax 2: CS-430.1 Sepax cell separation kit - Box of 6 Units

Published on: 03/13/2020	Addition of a second label in Chinese language.
Published on: 05/13/2019	Pre-notification for Sepax and Sefia, material change in component
Published on: 02/08/2019	Change in manufacturing of component for Sepax™ and Sefia™

Sepax 2: CS-470.0 Sepax cell separation kit - Box of 12 Units

Published on: 03/13/2020	Addition of a second label in Chinese language.
Published on: 10/03/2019	Update to Pre-notification for Sepax and Sefia, material change in component
Published on: 05/13/2019	Pre-notification for Sepax and Sefia, material change in component
Published on: 02/08/2019	Change in manufacturing of component for Sepax™ and Sefia™

Sepax 2: CS-470.1 Sepax cell separation kit - Box of 12 Units

Published on: 10/03/2019	Update to Pre-notification for Sepax and Sefia, material change in component
Published on: 05/13/2019	Pre-notification for Sepax and Sefia, material change in component
Published on: 02/08/2019	Change in manufacturing of component for Sepax™ and Sefia™

Sepax 2: CS-490.1 Sepax cell separation kit - Box of 6 Units

Published on: 03/13/2020	Addition of a second label in Chinese language.
Published on: 10/03/2019	Update to Pre-notification for Sepax and Sefia, material change in component
Published on: 05/13/2019	Pre-notification for Sepax and Sefia, material change in component
Published on: 02/08/2019	Change in manufacturing of component for Sepax™ and Sefia™

Sepax 2: CS-530.1 Sepax cell separation kit - Box of 6 Units

Published on: 10/03/2019	Update to Pre-notification for Sepax and Sefia, material change in component
Published on: 05/13/2019	Pre-notification for Sepax and Sefia, material change in component
Published on: 02/08/2019	Change in manufacturing of component for Sepax™ and Sefia™

Sepax 2: CS-530.4 Sepax cell separation kit - Box of 6 Units

Published on: 10/03/2019	Update to Pre-notification for Sepax and Sefia, material change in component
Published on: 05/13/2019	Pre-notification for Sepax and Sefia, material change in component
Published on: 02/08/2019	Change in manufacturing of component for Sepax™ and Sefia™

Sepax 2: CS-530.4b Sepax cell separation kit - Box of 6 Units

Published on: 10/03/2019	Update to Pre-notification for Sepax and Sefia, material change in component
Published on: 05/13/2019	Pre-notification for Sepax and Sefia, material change in component
Published on: 02/08/2019	Change in manufacturing of component for Sepax™ and Sefia™

Sepax 2: CS-540.4 Sepax cell separation kit - Box of 6 Units

Published on: 10/03/2019	Update to Pre-notification for Sepax and Sefia, material change in component
Published on: 05/13/2019	Pre-notification for Sepax and Sefia, material change in component
Published on: 02/08/2019	Change in manufacturing of component for Sepax™ and Sefia™

Sepax 2: CS-540.4b Sepax cell separation kit - Box of 6 Units

Published on: 10/03/2019	Update to Pre-notification for Sepax and Sefia, material change in component
Published on: 05/13/2019	Pre-notification for Sepax and Sefia, material change in component
Published on: 02/08/2019	Change in manufacturing of component for Sepax™ and Sefia™

Sepax 2: CS-570.3m Sepax Cell Separation Kit - Box of 20 Units

Published on: 10/03/2019	Update to Pre-notification for Sepax and Sefia, material change in component
Published on: 05/13/2019	Pre-notification for Sepax and Sefia, material change in component
Published on: 02/08/2019	Change in manufacturing of component for Sepax™ and Sefia™

Sepax 2: CS-570.4 Sepax cell separation kit - Box of 12 Units

Published on: 10/03/2019	Update to Pre-notification for Sepax and Sefia, material change in component
Published on: 05/13/2019	Pre-notification for Sepax and Sefia, material change in component
Published on: 02/08/2019	Change in manufacturing of component for Sepax™ and Sefia™

Sepax 2: CS-570.4mb Sepax cell separation kit - Box of 20 Units

Published on: 10/03/2019	Update to Pre-notification for Sepax and Sefia, material change in component
Published on: 05/13/2019	Pre-notification for Sepax and Sefia, material change in component
Published on: 02/08/2019	Change in manufacturing of component for Sepax™ and Sefia™

Sepax 2: CS-600.1 Sepax cell separation kit - Box of 6 Units

Published on: 05/04/2020	Updated Certificate of Analysis for CS-600.1 and CT-60.1 due to changed QC sampling
Published on: 03/13/2020	Addition of a second label in Chinese language.
Published on: 10/03/2019	Update to Pre-notification for Sepax and Sefia, material change in component
Published on: 05/13/2019	Pre-notification for Sepax and Sefia, material change in component
Published on: 02/08/2019	Change in manufacturing of component for Sepax™ and Sefia™

Sepax 2: CS-900.2 Sepax cell separation kit - Box of 6 Units

Published on: 03/13/2020	Addition of a second label in Chinese language.
Published on: 10/03/2019	Update to Pre-notification for Sepax and Sefia, material change in component
Published on: 05/13/2019	Pre-notification for Sepax and Sefia, material change in component
Published on: 02/08/2019	Change in manufacturing of component for Sepax™ and Sefia™
Published on: 12/17/2018	Changes in control work procedure for Sepax Cell processing kit.

Sepax 2: CultureWash Sepax 2 protocol software

Published on: 02/22/2019	Change to the CultureWash Sepax C-Pro protocol software v432
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Sepax 2: FB-100.2 - Box of 24 Units

Published on: 03/13/2020	Addition of a second label in Chinese language.
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Sepax 2: RCP-100 - Box of 3 Units

Published on: 10/03/2019	Update to Pre-notification for Sepax and Sefia, material change in component
Published on: 05/13/2019	Pre-notification for Sepax and Sefia, material change in component
Published on: 02/08/2019	Change in manufacturing of component for Sepax™ and Sefia™

Sepax C-Pro

Published on: 04/24/2020	Impact on Cell & Gene Therapy non-medical device products produced in Eysins, Switzerland since GE Healthcare Life Sciences (Biopharma business) is
Published on: 02/07/2020	Sepax TeamViewer software update
Published on: 11/20/2019	New version of Sepax software operating system
Published on: 08/30/2019	Sepax and Sefia instruments, component change
Published on: 07/24/2019	Pre-notification regarding Sepax and Sefia machines - component machine change
Published on: 07/16/2019	Pre-notification regarding Microsoft Windows Operating System Security Vulnerability

Sepax C-Pro: BeadWash Sepax C-Pro protocol software

Published on: 04/24/2020	Impact on Cell & Gene Therapy non-medical device products produced in Eysins, Switzerland since GE Healthcare Life Sciences (Biopharma business) is
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Sepax C-Pro: CT-49.1 - Box of 6 Units

Published on: 04/24/2020	Impact on Cell & Gene Therapy non-medical device products produced in Eysins, Switzerland since GE Healthcare Life Sciences (Biopharma business) is
Published on: 10/03/2019	Update to Pre-notification for Sepax and Sefia, material change in component
Published on: 05/13/2019	Pre-notification for Sepax and Sefia, material change in component
Published on: 02/08/2019	Change in manufacturing of component for Sepax™ and Sefia™

Sepax C-Pro: CT-60.1 - Box of 6 Units

Published on: 05/04/2020	Updated Certificate of Analysis for CS-600.1 and CT-60.1 due to changed QC sampling
Published on: 04/24/2020	Impact on Cell & Gene Therapy non-medical device products produced in Eysins, Switzerland since GE Healthcare Life Sciences (Biopharma business) is
Published on: 10/03/2019	Update to Pre-notification for Sepax and Sefia, material change in component
Published on: 05/13/2019	Pre-notification for Sepax and Sefia, material change in component
Published on: 02/08/2019	Change in manufacturing of component for Sepax™ and Sefia™

Sepax C-Pro: CT-90.1 - Box of 6 Units

Published on: 04/24/2020	Impact on Cell & Gene Therapy non-medical device products produced in Eysins, Switzerland since GE Healthcare Life Sciences (Biopharma business) is
Published on: 10/03/2019	Update to Pre-notification for Sepax and Sefia, material change in component
Published on: 05/13/2019	Pre-notification for Sepax and Sefia, material change in component
Published on: 02/08/2019	Change in manufacturing of component for Sepax™ and Sefia™
Published on: 12/17/2018	Changes in control work procedure for Sepax Cell processing kit.

Sepax C-Pro: CultureWash Sepax C-Pro protocol software

Published on: 04/24/2020	Impact on Cell & Gene Therapy non-medical device products produced in Eysins, Switzerland since GE Healthcare Life Sciences (Biopharma business) is
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Sepax C-Pro: Dilution Sepax C-Pro protocol software

Published on: 04/24/2020	Impact on Cell & Gene Therapy non-medical device products produced in Eysins, Switzerland since GE Healthcare Life Sciences (Biopharma business) is
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Sepax C-Pro: Neatcell Sepax C-Pro protocol software

Published on: 04/24/2020	Impact on Cell & Gene Therapy non-medical device products produced in Eysins, Switzerland since GE Healthcare Life Sciences (Biopharma business) is
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Sepax C-Pro: Pericell Sepax C-Pro protocol software

Published on: 04/24/2020	Impact on Cell & Gene Therapy non-medical device products produced in Eysins, Switzerland since GE Healthcare Life Sciences (Biopharma business) is
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Sepax C-Pro: Plateletfree Sepax C-Pro protocol software

Published on: 04/24/2020	Impact on Cell & Gene Therapy non-medical device products produced in Eysins, Switzerland since GE Healthcare Life Sciences (Biopharma business) is
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SepaxNet 2 Computer

Published on: 04/09/2020	SepaxNet Discontinuation
Published on: 07/16/2019	Pre-notification regarding Microsoft Windows Operating System Security Vulnerability
Published on: 06/20/2019	SepaxNet 2 hardware change

SepaxNet 2 Traceability System

Published on: 04/09/2020	SepaxNet Discontinuation
Published on: 07/16/2019	Pre-notification regarding Microsoft Windows Operating System Security Vulnerability
Published on: 06/20/2019	SepaxNet 2 hardware change

Smart-Max AS-310

Published on: 07/16/2019 Pre-notification regarding Microsoft Windows Operating System Security Vulnerability

Smart-Max: FA-100.1 Smart-Max cryopreparation accessory - Box of 24 Units

Published on: 03/13/2020 Addition of a second label in Chinese language.

Xuri Cell Expansion System W25

Published on: 04/29/2020 Microsoft vulnerability patches for Wave25 and Xuri25 EPC_29-Apr-2020

Published on: 04/27/2020 Microsoft vulnerability patches for Wave25 and Xuri25 EPC_27-Apr-2020

Published on: 10/01/2018 New EPC board for WAVE 25 o Xuri 25_CCN 01Oct2018

Xuri Cell Expansion System W5

Published on: 05/06/2020 Discontinuation of Xuri Cell Expansion System W5 products_CCN 06-May-2020

Published on: 08/13/2019 190813RCWC-1 - Revision to Certificate of Quality for ReadyCircuit™ Assembly

Xuri Cellbag 10L Basic

Published on: 05/15/2020 TW392538-W_CCN update new labels and certificate of quality

Published on: 05/15/2020 200515MXWM-1 - Bag manufacturing process change and new equipment introduction for single-use products manufactured in Westborough, MA, US

Published on: 04/03/2020 200403MXWM-1 Gamma irradiation dose range change

Published on: 03/20/2020 200320MXWO-0_GEHC LS Prenotification for Capacity Changes

Published on: 01/24/2020 200124XUWC-1 Xuri Certificate of Quality template change

Published on: 09/10/2019 190910MXWR-0: Pre-Notification of Replacement of TPE tubing in GE Healthcare Single-Use Assemblies

Published on: 04/17/2018 GEHC LS: Process Change for Westborough, MA Manufactured Single-Use Irradiated Products

Xuri Cellbag 10L DOOPT II and pHOPT

Published on: 05/15/2020 TW392538-W_CCN update new labels and certificate of quality

Published on: 05/15/2020 200515MXWM-1 - Bag manufacturing process change and new equipment introduction for single-use products manufactured in Westborough, MA, US

Published on: 04/03/2020 200403MXWM-1 Gamma irradiation dose range change

Published on: 03/20/2020 200320MXWO-0_GEHC LS Prenotification for Capacity Changes

Published on: 01/24/2020 200124XUWC-1 Xuri Certificate of Quality template change

Published on: 09/10/2019 190910MXWR-0: Pre-Notification of Replacement of TPE tubing in GE Healthcare Single-Use Assemblies

Published on: 04/17/2018 GEHC LS: Process Change for Westborough, MA Manufactured Single-Use Irradiated Products

Xuri Cellbag 10L DOOPT II, pHOPT and Perfusion

Published on: 05/15/2020 TW392538-W_CCN update new labels and certificate of quality

Published on: 05/15/2020
Published on: 04/03/2020
Published on: 03/20/2020
Published on: 01/24/2020
Published on: 09/10/2019
Published on: 06/20/2018
Published on: 04/17/2018

200515MXWM-1 - Bag manufacturing process change and new equipment introduction for single-use products manufactured in Westborough, MA, US
200403MXWM-1 Gamma irradiation dose range change
200320MXWO-0_GEHC LS Prenotification for Capacity Changes
200124XUWC-1 Xuri Certificate of Quality template change
190910MXWR-0: Pre-Notification of Replacement of TPE tubing in GE Healthcare Single-Use Assemblies
Changes for Oxywell™ 2 Subassembly: WAVE™ and Xuri™ Cellbags- CCN 180620MXWR-1
GEHC LS: Process Change for Westborough, MA Manufactured Single-Use Irradiated Products

Xuri Cellbag 10L Perfusion

Published on: 05/15/2020
Published on: 05/15/2020
Published on: 04/03/2020
Published on: 03/20/2020
Published on: 01/24/2020
Published on: 09/10/2019
Published on: 06/20/2018
Published on: 04/17/2018

TW392538-W_CCN update new labels and certificate of quality
200515MXWM-1 - Bag manufacturing process change and new equipment introduction for single-use products manufactured in Westborough, MA, US
200403MXWM-1 Gamma irradiation dose range change
200320MXWO-0_GEHC LS Prenotification for Capacity Changes
200124XUWC-1 Xuri Certificate of Quality template change
190910MXWR-0: Pre-Notification of Replacement of TPE tubing in GE Healthcare Single-Use Assemblies
Changes for Oxywell™ 2 Subassembly: WAVE™ and Xuri™ Cellbags- CCN 180620MXWR-1
GEHC LS: Process Change for Westborough, MA Manufactured Single-Use Irradiated Products

Xuri Cellbag 20L DOOPT II and pHOPT

Published on: 05/15/2020
Published on: 05/15/2020
Published on: 04/03/2020
Published on: 03/20/2020
Published on: 01/24/2020
Published on: 10/28/2019
Published on: 09/13/2019
Published on: 09/10/2019
Published on: 04/17/2018

TW392538-W_CCN update new labels and certificate of quality
200515MXWM-1 - Bag manufacturing process change and new equipment introduction for single-use products manufactured in Westborough, MA, US
200403MXWM-1 Gamma irradiation dose range change
200320MXWO-0_GEHC LS Prenotification for Capacity Changes
200124XUWC-1 Xuri Certificate of Quality template change
190913MXWO-2_Pinch Clamp UPDATE
190913MXWO-1_Pinch Clamp Change Control Notification
190910MXWR-0: Pre-Notification of Replacement of TPE tubing in GE Healthcare Single-Use Assemblies
GEHC LS: Process Change for Westborough, MA Manufactured Single-Use Irradiated Products

Xuri Cellbag 20L DOOPT II, pHOPT and Perfusion

Published on: 05/15/2020
Published on: 05/15/2020
Published on: 04/03/2020
Published on: 03/20/2020
Published on: 01/24/2020
Published on: 10/28/2019

TW392538-W_CCN update new labels and certificate of quality
200515MXWM-1 - Bag manufacturing process change and new equipment introduction for single-use products manufactured in Westborough, MA, US
200403MXWM-1 Gamma irradiation dose range change
200320MXWO-0_GEHC LS Prenotification for Capacity Changes
200124XUWC-1 Xuri Certificate of Quality template change
190913MXWO-2_Pinch Clamp UPDATE

Published on: 09/13/2019
Published on: 09/10/2019
Published on: 04/17/2018

190913MXWO-1_Pinch Clamp Change Control Notification
190910MXWR-0: Pre-Notification of Replacement of TPE tubing in GE Healthcare Single-Use Assemblies
GEHC LS: Process Change for Westborough, MA Manufactured Single-Use Irradiated Products

Xuri Cellbag 2L Basic

Published on: 05/15/2020
Published on: 05/15/2020
Published on: 04/03/2020
Published on: 03/20/2020
Published on: 01/24/2020
Published on: 09/10/2019
Published on: 04/17/2018

TW392538-W_CCN update new labels and certificate of quality
200515MXWM-1 - Bag manufacturing process change and new equipment introduction for single-use products manufactured in Westborough, MA, US
200403MXWM-1 Gamma irradiation dose range change
200320MXWO-0_GEHC LS Prenotification for Capacity Changes
200124XUWC-1 Xuri Certificate of Quality template change
190910MXWR-0: Pre-Notification of Replacement of TPE tubing in GE Healthcare Single-Use Assemblies
GEHC LS: Process Change for Westborough, MA Manufactured Single-Use Irradiated Products

Xuri Cellbag 2L DOOPT II and pHOPT

Published on: 05/15/2020
Published on: 05/15/2020
Published on: 04/03/2020
Published on: 03/20/2020
Published on: 01/24/2020
Published on: 09/10/2019
Published on: 04/17/2018

TW392538-W_CCN update new labels and certificate of quality
200515MXWM-1 - Bag manufacturing process change and new equipment introduction for single-use products manufactured in Westborough, MA, US
200403MXWM-1 Gamma irradiation dose range change
200320MXWO-0_GEHC LS Prenotification for Capacity Changes
200124XUWC-1 Xuri Certificate of Quality template change
190910MXWR-0: Pre-Notification of Replacement of TPE tubing in GE Healthcare Single-Use Assemblies
GEHC LS: Process Change for Westborough, MA Manufactured Single-Use Irradiated Products

Xuri Cellbag 2L DOOPT II, pHOPT and Perfusion

Published on: 05/15/2020
Published on: 05/15/2020
Published on: 04/03/2020
Published on: 03/20/2020
Published on: 01/24/2020
Published on: 09/10/2019
Published on: 06/20/2018
Published on: 04/17/2018

TW392538-W_CCN update new labels and certificate of quality
200515MXWM-1 - Bag manufacturing process change and new equipment introduction for single-use products manufactured in Westborough, MA, US
200403MXWM-1 Gamma irradiation dose range change
200320MXWO-0_GEHC LS Prenotification for Capacity Changes
200124XUWC-1 Xuri Certificate of Quality template change
190910MXWR-0: Pre-Notification of Replacement of TPE tubing in GE Healthcare Single-Use Assemblies
Changes for Oxywell™ 2 Subassembly: WAVE™ and Xuri™ Cellbags- CCN 180620MXWR-1
GEHC LS: Process Change for Westborough, MA Manufactured Single-Use Irradiated Products

Xuri Cellbag 2L Perfusion

Published on: 05/15/2020
Published on: 05/15/2020

TW392538-W_CCN update new labels and certificate of quality
200515MXWM-1 - Bag manufacturing process change and new equipment introduction for single-use products manufactured in Westborough, MA, US

Published on: 04/03/2020	200403MXWM-1 Gamma irradiation dose range change
Published on: 03/20/2020	200320MXWO-0_GEHC LS Prenotification for Capacity Changes
Published on: 01/24/2020	200124XUWC-1 Xuri Certificate of Quality template change
Published on: 09/10/2019	190910MXWR-0: Pre-Notification of Replacement of TPE tubing in GE Healthcare Single-Use Assemblies
Published on: 06/20/2018	Changes for Oxywell™ 2 Subassembly: WAVE™ and Xuri™ Cellbags- CCN 180620MXWR-1
Published on: 04/17/2018	GEHC LS: Process Change for Westborough, MA Manufactured Single-Use Irradiated Products

Xuri Cellbag 50L DOOPT II and pHOPT

Published on: 05/15/2020	TW392538-W_CCN update new labels and certificate of quality
Published on: 05/15/2020	200515MXWM-1 - Bag manufacturing process change and new equipment introduction for single-use products manufactured in Westborough, MA, US
Published on: 04/03/2020	200403MXWM-1 Gamma irradiation dose range change
Published on: 03/20/2020	200320MXWO-0_GEHC LS Prenotification for Capacity Changes
Published on: 01/24/2020	200124XUWC-1 Xuri Certificate of Quality template change
Published on: 09/10/2019	190910MXWR-0: Pre-Notification of Replacement of TPE tubing in GE Healthcare Single-Use Assemblies
Published on: 04/17/2018	GEHC LS: Process Change for Westborough, MA Manufactured Single-Use Irradiated Products

Xuri Cellbag 50L DOOPT II, pHOPT and Perfusion

Published on: 05/15/2020	TW392538-W_CCN update new labels and certificate of quality
Published on: 05/15/2020	200515MXWM-1 - Bag manufacturing process change and new equipment introduction for single-use products manufactured in Westborough, MA, US
Published on: 04/03/2020	200403MXWM-1 Gamma irradiation dose range change
Published on: 03/20/2020	200320MXWO-0_GEHC LS Prenotification for Capacity Changes
Published on: 01/24/2020	200124XUWC-1 Xuri Certificate of Quality template change
Published on: 09/10/2019	190910MXWR-0: Pre-Notification of Replacement of TPE tubing in GE Healthcare Single-Use Assemblies
Published on: 04/17/2018	GEHC LS: Process Change for Westborough, MA Manufactured Single-Use Irradiated Products

Xuri Cellbag, 10L, BC10, Basic

Published on: 05/15/2020	TW392538-W_CCN update new labels and certificate of quality
Published on: 05/15/2020	200515MXWM-1 - Bag manufacturing process change and new equipment introduction for single-use products manufactured in Westborough, MA, US
Published on: 04/03/2020	200403MXWM-1 Gamma irradiation dose range change
Published on: 03/20/2020	200320MXWO-0_GEHC LS Prenotification for Capacity Changes
Published on: 01/24/2020	200124XUWC-1 Xuri Certificate of Quality template change
Published on: 09/10/2019	190910MXWR-0: Pre-Notification of Replacement of TPE tubing in GE Healthcare Single-Use Assemblies
Published on: 04/17/2018	GEHC LS: Process Change for Westborough, MA Manufactured Single-Use Irradiated Products

Xuri Cellbag, 10L, BC10, Perf, DO

Published on: 05/15/2020	TW392538-W_CCN update new labels and certificate of quality
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Published on: 05/15/2020
Published on: 04/03/2020
Published on: 03/20/2020
Published on: 01/24/2020
Published on: 09/10/2019
Published on: 06/20/2018
Published on: 04/17/2018

200515MXWM-1 - Bag manufacturing process change and new equipment introduction for single-use products manufactured in Westborough, MA, US
200403MXWM-1 Gamma irradiation dose range change
200320MXWO-0_GEHC LS Prenotification for Capacity Changes
200124XUWC-1 Xuri Certificate of Quality template change
190910MXWR-0: Pre-Notification of Replacement of TPE tubing in GE Healthcare Single-Use Assemblies
Changes for Oxywell™ 2 Subassembly: WAVE™ and Xuri™ Cellbags- CCN 180620MXWR-1
GEHC LS: Process Change for Westborough, MA Manufactured Single-Use Irradiated Products

Xuri Cellbag, 20L, BC10, Basic

Published on: 05/15/2020
Published on: 05/15/2020
Published on: 04/03/2020
Published on: 03/20/2020
Published on: 01/24/2020
Published on: 09/10/2019
Published on: 04/17/2018

TW392538-W_CCN update new labels and certificate of quality
200515MXWM-1 - Bag manufacturing process change and new equipment introduction for single-use products manufactured in Westborough, MA, US
200403MXWM-1 Gamma irradiation dose range change
200320MXWO-0_GEHC LS Prenotification for Capacity Changes
200124XUWC-1 Xuri Certificate of Quality template change
190910MXWR-0: Pre-Notification of Replacement of TPE tubing in GE Healthcare Single-Use Assemblies
GEHC LS: Process Change for Westborough, MA Manufactured Single-Use Irradiated Products

Xuri Cellbag, 20L, BC10, Perf, DO

Published on: 05/15/2020
Published on: 05/15/2020
Published on: 04/03/2020
Published on: 03/20/2020
Published on: 01/24/2020
Published on: 09/10/2019
Published on: 06/20/2018
Published on: 04/17/2018

TW392538-W_CCN update new labels and certificate of quality
200515MXWM-1 - Bag manufacturing process change and new equipment introduction for single-use products manufactured in Westborough, MA, US
200403MXWM-1 Gamma irradiation dose range change
200320MXWO-0_GEHC LS Prenotification for Capacity Changes
200124XUWC-1 Xuri Certificate of Quality template change
190910MXWR-0: Pre-Notification of Replacement of TPE tubing in GE Healthcare Single-Use Assemblies
Changes for Oxywell™ 2 Subassembly: WAVE™ and Xuri™ Cellbags- CCN 180620MXWR-1
GEHC LS: Process Change for Westborough, MA Manufactured Single-Use Irradiated Products

Xuri Cellbag, 20L, BC10, pH, DO

Published on: 05/15/2020
Published on: 05/15/2020
Published on: 04/03/2020
Published on: 03/20/2020
Published on: 01/24/2020
Published on: 09/10/2019
Published on: 06/20/2018
Published on: 04/17/2018

TW392538-W_CCN update new labels and certificate of quality
200515MXWM-1 - Bag manufacturing process change and new equipment introduction for single-use products manufactured in Westborough, MA, US
200403MXWM-1 Gamma irradiation dose range change
200320MXWO-0_GEHC LS Prenotification for Capacity Changes
200124XUWC-1 Xuri Certificate of Quality template change
190910MXWR-0: Pre-Notification of Replacement of TPE tubing in GE Healthcare Single-Use Assemblies
Changes for Oxywell™ 2 Subassembly: WAVE™ and Xuri™ Cellbags- CCN 180620MXWR-1
GEHC LS: Process Change for Westborough, MA Manufactured Single-Use Irradiated Products

Xuri Cellbag, 2L, BC10, Basic

Published on: 05/15/2020

TW392538-W_CCN update new labels and certificate of quality

Published on: 05/15/2020

200515MXWM-1 - Bag manufacturing process change and new equipment introduction for single-use products manufactured in Westborough, MA, US

Published on: 04/03/2020

200403MXWM-1 Gamma irradiation dose range change

Published on: 03/20/2020

200320MXWO-0_GEHC LS Prenotification for Capacity Changes

Published on: 01/24/2020

200124XUWC-1 Xuri Certificate of Quality template change

Published on: 09/10/2019

190910MXWR-0: Pre-Notification of Replacement of TPE tubing in GE Healthcare Single-Use Assemblies

Published on: 06/20/2018

Changes for Oxywell™ 2 Subassembly: WAVE™ and Xuri™ Cellbags- CCN 180620MXWR-1

Published on: 04/17/2018

GEHC LS: Process Change for Westborough, MA Manufactured Single-Use Irradiated Products

Xuri Cellbag, 2L, BC10, Perf, DO

Published on: 05/15/2020

TW392538-W_CCN update new labels and certificate of quality

Published on: 05/15/2020

200515MXWM-1 - Bag manufacturing process change and new equipment introduction for single-use products manufactured in Westborough, MA, US

Published on: 04/03/2020

200403MXWM-1 Gamma irradiation dose range change

Published on: 03/20/2020

200320MXWO-0_GEHC LS Prenotification for Capacity Changes

Published on: 01/24/2020

200124XUWC-1 Xuri Certificate of Quality template change

Published on: 09/10/2019

190910MXWR-0: Pre-Notification of Replacement of TPE tubing in GE Healthcare Single-Use Assemblies

Published on: 06/20/2018

Changes for Oxywell™ 2 Subassembly: WAVE™ and Xuri™ Cellbags- CCN 180620MXWR-1

Published on: 04/17/2018

GEHC LS: Process Change for Westborough, MA Manufactured Single-Use Irradiated Products

Xuri Cellbag, 2L, BC10, Screw, DO

Published on: 05/15/2020

TW392538-W_CCN update new labels and certificate of quality

Published on: 05/15/2020

200515MXWM-1 - Bag manufacturing process change and new equipment introduction for single-use products manufactured in Westborough, MA, US

Published on: 04/03/2020

200403MXWM-1 Gamma irradiation dose range change

Published on: 03/20/2020

200320MXWO-0_GEHC LS Prenotification for Capacity Changes

Published on: 01/24/2020

200124XUWC-1 Xuri Certificate of Quality template change

Published on: 09/10/2019

190910MXWR-0: Pre-Notification of Replacement of TPE tubing in GE Healthcare Single-Use Assemblies

Published on: 06/20/2018

Changes for Oxywell™ 2 Subassembly: WAVE™ and Xuri™ Cellbags- CCN 180620MXWR-1

Published on: 04/17/2018

GEHC LS: Process Change for Westborough, MA Manufactured Single-Use Irradiated Products

Xuri Cellbag, 50L, BC10, Basic

Published on: 05/15/2020

TW392538-W_CCN update new labels and certificate of quality

Published on: 05/15/2020

200515MXWM-1 - Bag manufacturing process change and new equipment introduction for single-use products manufactured in Westborough, MA, US

Published on: 04/03/2020

200403MXWM-1 Gamma irradiation dose range change

Published on: 03/20/2020

200320MXWO-0_GEHC LS Prenotification for Capacity Changes

Published on: 01/24/2020
Published on: 09/10/2019
Published on: 04/17/2018

200124XUWC-1 Xuri Certificate of Quality template change
190910MXWR-0: Pre-Notification of Replacement of TPE tubing in GE Healthcare Single-Use Assemblies
GEHC LS: Process Change for Westborough, MA Manufactured Single-Use Irradiated Products

Xuri CP CELLBAG 2L PERF

Published on: 05/15/2020
Published on: 05/15/2020
Published on: 04/03/2020
Published on: 03/20/2020
Published on: 01/24/2020
Published on: 09/10/2019
Published on: 06/20/2018
Published on: 05/14/2018
Published on: 04/17/2018

TW392538-W_CCN update new labels and certificate of quality
200515MXWM-1 - Bag manufacturing process change and new equipment introduction for single-use products manufactured in Westborough, MA, US
200403MXWM-1 Gamma irradiation dose range change
200320MXWO-0_GEHC LS Prenotification for Capacity Changes
200124XUWC-1 Xuri Certificate of Quality template change
190910MXWR-0: Pre-Notification of Replacement of TPE tubing in GE Healthcare Single-Use Assemblies
Changes for Oxywell™ 2 Subassembly: WAVE™ and Xuri™ Cellbags- CCN 180620MXWR-1
Xuri™ 1.2 um SP/CP Cellbag™ Shelf Life Extension and update to Certificate of Quality and product labeling, 180515XUWO-1
GEHC LS: Process Change for Westborough, MA Manufactured Single-Use Irradiated Products

Xuri CP CELLBAG 2L PERF pH DO

Published on: 05/15/2020
Published on: 05/15/2020
Published on: 04/03/2020
Published on: 03/20/2020
Published on: 01/24/2020
Published on: 09/10/2019
Published on: 06/20/2018
Published on: 05/14/2018
Published on: 04/17/2018

TW392538-W_CCN update new labels and certificate of quality
200515MXWM-1 - Bag manufacturing process change and new equipment introduction for single-use products manufactured in Westborough, MA, US
200403MXWM-1 Gamma irradiation dose range change
200320MXWO-0_GEHC LS Prenotification for Capacity Changes
200124XUWC-1 Xuri Certificate of Quality template change
190910MXWR-0: Pre-Notification of Replacement of TPE tubing in GE Healthcare Single-Use Assemblies
Changes for Oxywell™ 2 Subassembly: WAVE™ and Xuri™ Cellbags- CCN 180620MXWR-1
Xuri™ 1.2 um SP/CP Cellbag™ Shelf Life Extension and update to Certificate of Quality and product labeling, 180515XUWO-1
GEHC LS: Process Change for Westborough, MA Manufactured Single-Use Irradiated Products

Xuri SP CELLBAG 10L PERF

Published on: 05/15/2020
Published on: 05/15/2020
Published on: 04/03/2020
Published on: 03/20/2020
Published on: 01/24/2020
Published on: 01/24/2020
Published on: 09/10/2019
Published on: 06/20/2018

TW392538-W_CCN update new labels and certificate of quality
200515MXWM-1 - Bag manufacturing process change and new equipment introduction for single-use products manufactured in Westborough, MA, US
200403MXWM-1 Gamma irradiation dose range change
200320MXWO-0_GEHC LS Prenotification for Capacity Changes
200124XUWC-1 Xuri Certificate of Quality template change
200124XUWL-1 Xuri product label change
190910MXWR-0: Pre-Notification of Replacement of TPE tubing in GE Healthcare Single-Use Assemblies
Changes for Oxywell™ 2 Subassembly: WAVE™ and Xuri™ Cellbags- CCN 180620MXWR-1

Published on: 05/14/2018
Published on: 04/17/2018

Xuri™ 1.2 um SP/CP Cellbag™ Shelf Life Extension and update to Certificate of Quality and product labeling, 180515XUWO-1
GEHC LS: Process Change for Westborough, MA Manufactured Single-Use Irradiated Products

Xuri SP CELLBAG 10L PERF pH DO

Published on: 05/15/2020
Published on: 05/15/2020
Published on: 04/03/2020
Published on: 03/20/2020
Published on: 01/24/2020
Published on: 01/24/2020
Published on: 09/10/2019
Published on: 06/20/2018
Published on: 05/14/2018
Published on: 04/17/2018

TW392538-W_CCN update new labels and certificate of quality
200515MXWM-1 - Bag manufacturing process change and new equipment introduction for single-use products manufactured in Westborough, MA, US
200403MXWM-1 Gamma irradiation dose range change
200320MXWO-0_GEHC LS Prenotification for Capacity Changes
200124XUWC-1 Xuri Certificate of Quality template change
200124XUWL-1 Xuri product label change
190910MXWR-0: Pre-Notification of Replacement of TPE tubing in GE Healthcare Single-Use Assemblies
Changes for Oxywell™ 2 Subassembly: WAVE™ and Xuri™ Cellbags- CCN 180620MXWR-1
Xuri™ 1.2 um SP/CP Cellbag™ Shelf Life Extension and update to Certificate of Quality and product labeling, 180515XUWO-1
GEHC LS: Process Change for Westborough, MA Manufactured Single-Use Irradiated Products

Xuri SP CELLBAG 2L PERF

Published on: 05/15/2020
Published on: 05/15/2020
Published on: 04/03/2020
Published on: 03/20/2020
Published on: 01/24/2020
Published on: 09/10/2019
Published on: 06/20/2018
Published on: 05/14/2018
Published on: 04/17/2018

TW392538-W_CCN update new labels and certificate of quality
200515MXWM-1 - Bag manufacturing process change and new equipment introduction for single-use products manufactured in Westborough, MA, US
200403MXWM-1 Gamma irradiation dose range change
200320MXWO-0_GEHC LS Prenotification for Capacity Changes
200124XUWC-1 Xuri Certificate of Quality template change
190910MXWR-0: Pre-Notification of Replacement of TPE tubing in GE Healthcare Single-Use Assemblies
Changes for Oxywell™ 2 Subassembly: WAVE™ and Xuri™ Cellbags- CCN 180620MXWR-1
Xuri™ 1.2 um SP/CP Cellbag™ Shelf Life Extension and update to Certificate of Quality and product labeling, 180515XUWO-1
GEHC LS: Process Change for Westborough, MA Manufactured Single-Use Irradiated Products

Xuri SP CELLBAG 2L PERF pH DO

Published on: 05/15/2020
Published on: 05/15/2020
Published on: 04/03/2020
Published on: 03/20/2020
Published on: 01/24/2020
Published on: 09/10/2019
Published on: 06/20/2018
Published on: 05/14/2018
Published on: 04/17/2018

TW392538-W_CCN update new labels and certificate of quality
200515MXWM-1 - Bag manufacturing process change and new equipment introduction for single-use products manufactured in Westborough, MA, US
200403MXWM-1 Gamma irradiation dose range change
200320MXWO-0_GEHC LS Prenotification for Capacity Changes
200124XUWC-1 Xuri Certificate of Quality template change
190910MXWR-0: Pre-Notification of Replacement of TPE tubing in GE Healthcare Single-Use Assemblies
Changes for Oxywell™ 2 Subassembly: WAVE™ and Xuri™ Cellbags- CCN 180620MXWR-1
Xuri™ 1.2 um SP/CP Cellbag™ Shelf Life Extension and update to Certificate of Quality and product labeling, 180515XUWO-1
GEHC LS: Process Change for Westborough, MA Manufactured Single-Use Irradiated Products

Change Control Notification - Chromatography Resins

Global Notifications

Published on: 05/15/2020	Notification on Legal Entity changes
Published on: 05/14/2020	Final reminder for Notification on re-designed web page for Change Notifications and Regulatory Support Documentation
Published on: 05/11/2020	Reminder for Notification on re-designed web page for Change Notifications and Regulatory Support Documentation.
Published on: 04/27/2020	Update on Notification on re-designed web page for Change Notifications and Regulatory Support Documentation.
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Published on: 04/01/2020	Notification on change of company name
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Published on: 12/20/2019	Correction to notification regarding Legal entity changes for China
Published on: 11/29/2019	Notification on Legal Entity changes for Russia, China and India
Published on: 10/14/2019	Notification on Company Brand name and Legal Entity changes
Published on: 10/01/2019	Update to Pre-notification on new RS web page published 08 July 2019
Published on: 09/06/2019	Notification on Legal Entity changes - Correction
Published on: 08/30/2019	Notification on Legal Entity changes
Published on: 07/15/2019	Pre-notification on change of company name
Published on: 07/08/2019	Pre-notification new Regulatory Support web page
Published on: 06/11/2019	A GE Healthcare Life Sciences Notification
Published on: 07/06/2018	Update of GE Healthcare Life Sciences' Change Control Standard
Published on: 05/28/2018	Update of label for chromatography resins and ReadyToProcess columns
Published on: 03/05/2018	Update of GE Healthcare Life Sciences' Change Control Standard

AH Sepharose 4B

Published on: 09/24/2019	Updated Analytical specification for AH Sepharose 4B
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ANX Sepharose 4 Fast Flow (high sub)

Published on: 12/16/2019	Change to packaging material for package size 40L and 60L
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AVB Sepharose High Performance

Published on: 02/21/2019	Update on: New production line undergoing qualification for intended use
Published on: 04/10/2018	New production line undergoing qualification for intended use

Benzamidine Sepharose 4 Fast Flow (high sub)

Published on: 07/04/2019	Update on: New production line undergoing qualification for intended use
Published on: 04/10/2018	New production line undergoing qualification for intended use

Benzamidine Sepharose 4 Fast Flow (low sub)

Published on: 07/04/2019	Update on: New production line undergoing qualification for intended use
Published on: 04/10/2018	New production line undergoing qualification for intended use

Butyl Sepharose High Performance

Published on: 12/16/2019	Change to packaging material for package size 40L and 60L
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Butyl-S Sepharose 6 Fast Flow

Published on: 01/29/2019	Second supplier of raw material
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Capto adhere

Published on: 12/16/2019	Change to packaging material for package size 40L and 60L
Published on: 09/27/2019	Introduction of additional base matrix and Capto adhere manufacturing lines.

Capto Blue

Published on: 09/27/2019	Introduction of additional base matrix and Capto adhere manufacturing lines.
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Capto Blue (high sub)

Published on: 12/16/2019	Change to packaging material for package size 40L and 60L
Published on: 09/27/2019	Introduction of additional base matrix and Capto adhere manufacturing lines.

Capto Butyl

Published on: 09/27/2019	Introduction of additional base matrix and Capto adhere manufacturing lines.
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Capto Chelating

Published on: 09/27/2019	Introduction of additional base matrix and Capto adhere manufacturing lines.
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Capto Core 700

Published on: 01/31/2020	Update regarding the introduction of new base matrix manufacturing line within existing manufacturing area at the Uppsala site
Published on: 12/16/2019	Change to packaging material for package size 40L and 60L
Published on: 04/02/2019	Introduction of additional base matrix manufacturing lines

Capto DEAE

Published on: 05/08/2020	Extended shelf life for Capto DEAE
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Published on: 12/16/2019	Change to packaging material for package size 40L and 60L
Capto L	
Published on: 01/31/2020	Update regarding the introduction of new base matrix manufacturing line within existing manufacturing area at the Uppsala site
Published on: 04/23/2019	Insourcing of Protein L ligand manufacturing
Published on: 04/02/2019	Introduction of additional base matrix manufacturing lines
Capto MMC	
Published on: 12/16/2019	Change to packaging material for package size 40L and 60L
Capto Octyl	
Published on: 09/27/2019	Introduction of additional base matrix and Capto adhere manufacturing lines.
Published on: 11/09/2018	Second supplier of raw material
Capto Phenyl (high sub)	
Published on: 12/16/2019	Change to packaging material for package size 40L and 60L
Published on: 09/27/2019	Introduction of additional base matrix and Capto adhere manufacturing lines.
Capto Q	-
Published on: 12/16/2019	Change to packaging material for package size 40L and 60L
Capto S	-
Published on: 12/16/2019	Change to packaging material for package size 40L and 60L
Capto S ImpAct	-
Published on: 12/16/2019	Change to packaging material for package size 40L and 60L
Chelating Sepharose Big Beads	-
Published on: 02/25/2020	Second supplier of raw material
CM Sepharose Fast Flow	-
Published on: 12/16/2019	Change to packaging material for package size 40L and 60L
Published on: 07/05/2019	A GE Healthcare Life Sciences Notification
Published on: 05/02/2018	Correction to Updated analytical specification CM Sepharose Fast Flow
Published on: 04/20/2018	Updated analytical specification
CM32 AIE CELLULOSE	

Published on: 04/06/2020 Contract manufacturing of Whatman chromatography resins
Published on: 01/23/2019 Change of packaging material

CM52 AIE CELLULOSE

Published on: 04/06/2020 Contract manufacturing of Whatman chromatography resins
Published on: 01/23/2019 Change of packaging material

CNBr-activated Sepharose 4 Fast Flow

Published on: 02/20/2019 Updated Analytical specification for CNBr-activated Sepharose 4 Fast Flow.

CNBr-activated Sepharose 4B

Published on: 02/20/2019 Updated Analytical specification CNBr-activated Sepharose 4B

Cytodex 1

Published on: 04/17/2018 Updated analytical specification

Cytodex 1 Gamma

Published on: 06/19/2019 Updated Analytical Specification Cytodex 1 Gamma and Cytodex 3 Gamma TW 364175
Published on: 04/17/2018 Updated analytical specification

Cytodex 3 Gamma

Published on: 06/19/2019 Updated Analytical Specification Cytodex 1 Gamma and Cytodex 3 Gamma TW 364175
Published on: 04/17/2018 Updated analytical specification

Cytopore 1

Published on: 01/19/2018 Updated analytical specification and certificate of analysis

Cytopore 2

Published on: 01/19/2018 Updated analytical specification and certificate of analysis

DE32 AIE CELLULOSE

Published on: 04/06/2020 Contract manufacturing of Whatman chromatography resins
Published on: 01/23/2019 Change of packaging material

DE52 AIE CELLULOSE

Published on: 04/06/2020
Published on: 01/23/2019

Contract manufacturing of Whatman chromatography resins
Change of packaging material

DEAE Sephadex A-50

Published on: 06/25/2018

Second supplier of raw material fractionated dextran

DEAE Sepharose Fast Flow

Published on: 12/16/2019

Change to packaging material for package size 40L and 60L

Published on: 04/24/2018

Correction to Updated analytical specification DEAE Sepharose Fast Flow

Published on: 04/20/2018

Updated analytical specification

ECH-Lysine Sepharose 4 Fast Flow

Published on: 02/21/2019

Update on: New production line undergoing qualification for intended use

Published on: 04/10/2018

New production line undergoing qualification for intended use

Factor VII Select

Published on: 09/27/2019

Introduction of additional base matrix and Capto adhere manufacturing lines.

Published on: 09/24/2018

Extended shelf life

Gelatin Sepharose 4 Fast Flow

Published on: 02/21/2019

Update on: New production line undergoing qualification for intended use

Published on: 04/10/2018

New production line undergoing qualification for intended use

Gelatin Sepharose 4B

Published on: 12/13/2019

Update on: New production line undergoing qualification for intended use

Published on: 04/10/2018

New production line undergoing qualification for intended use

Heparin Sepharose CL-6B

Published on: 09/03/2019

Update on: New production line undergoing qualification for intended use

Published on: 04/10/2018

New production line undergoing qualification for intended use

HiTrap Q HP 1 ml

Published on: 03/07/2018

Updated Analytical Specification

HiTrap Q HP 5 ml

Published on: 03/07/2018

Updated Analytical Specification

IXSelect

Published on: 09/27/2019
Published on: 11/09/2018

Introduction of additional base matrix and Capto adhere manufacturing lines.
Second supplier of raw material

KappaSelect

Published on: 09/27/2019
Published on: 02/21/2019
Published on: 04/10/2018

Introduction of additional base matrix and Capto adhere manufacturing lines.
Update on: New production line undergoing qualification for intended use
New production line undergoing qualification for intended use

LambdaFabSelect

Published on: 09/27/2019

Introduction of additional base matrix and Capto adhere manufacturing lines.

Lentil Lectin Sepharose 4B

Published on: 12/13/2019
Published on: 04/10/2018

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Update on: New production line undergoing qualification for intended use
New production line undergoing qualification for intended use

MabSelect

Published on: 02/12/2020
Published on: 05/07/2018

Insourcing of rProtein A ligand manufacturing
Introduction of alternative chemical used as reducing agent for Protein A ligand

MabSelect SuRe

Published on: 01/31/2020
Published on: 12/16/2019
Published on: 07/05/2019
Published on: 04/02/2019
Published on: 06/05/2018

Update regarding the introduction of new base matrix manufacturing line within existing manufacturing area at the Uppsala site
Change to packaging material for package size 40L and 60L
Insourcing of MabSelect SuRe ligand manufacturing
Introduction of additional base matrix manufacturing lines
Introduction of alternative chemical used as reducing agent for MabSelect SuRe ligand

MabSelect SuRe LX

Published on: 01/31/2020
Published on: 07/05/2019
Published on: 04/02/2019
Published on: 06/05/2018

Update regarding the introduction of new base matrix manufacturing line within existing manufacturing area at the Uppsala site
Insourcing of MabSelect SuRe ligand manufacturing
Introduction of additional base matrix manufacturing lines
Introduction of alternative chemical used as reducing agent for MabSelect SuRe ligand

MabSelect SuRe pcc

Published on: 07/05/2019
Published on: 06/05/2018

Insourcing of MabSelect SuRe ligand manufacturing
Introduction of alternative chemical used as reducing agent for MabSelect SuRe ligand

MabSelect Xtra

Published on: 02/12/2020

Insourcing of rProtein A ligand manufacturing

Published on: 12/16/2019

Change to packaging material for package size 40L and 60L

Published on: 06/05/2018

Introduction of alternative chemical used as reducing agent for rProtein A ligand

MacroCap SP

Published on: 12/16/2019

Change to packaging material for package size 40L and 60L

Mono Q

Published on: 12/13/2019

Correction to notification regarding discontinuation of Mono Q & Mono S

Published on: 05/02/2019

Discontinuation of Mono Q and Mono S product lines

Mono S

Published on: 12/13/2019

Correction to notification regarding discontinuation of Mono Q & Mono S

Published on: 05/02/2019

Discontinuation of Mono Q and Mono S product lines

Ni Sepharose 6 Fast Flow

Published on: 01/22/2019

Updated analytical specification

Phenyl Sepharose 6 Fast Flow (high sub)

Published on: 12/16/2019

Change to packaging material for package size 40L and 60L

Phenyl Sepharose 6 Fast Flow (high sub) Special Grade

Published on: 10/18/2019

Updated Analytical Specification

Phenyl Sepharose Big Beads

Published on: 02/25/2020

Second supplier of raw material

Phenyl Sepharose High Performance

Published on: 12/16/2019

Change to packaging material for package size 40L and 60L

PlasmidSelect

Published on: 05/24/2018

Discontinuation of PlasmidSelect

Plasminogen Removal Gel

Published on: 11/09/2018 Second supplier of raw material

Protein A Sepharose 6 Fast Flow

Published on: 12/13/2019 Update on: New production line undergoing qualification for intended use
Published on: 04/10/2018 New production line undergoing qualification for intended use

Protein A Sepharose CL-4B

Published on: 12/13/2019 Update on: New production line undergoing qualification for intended use
Published on: 09/13/2019 Updated Analytical specification for Protein A Sepharose CL-4B
Published on: 07/02/2019 Extended shelf life

Published on: 04/10/2018 New production line undergoing qualification for intended use

Protein G Sepharose 4 Fast Flow

Published on: 02/21/2019 Update on: New production line undergoing qualification for intended use
Published on: 05/04/2018 Updated information regarding animal origin
Published on: 04/10/2018 New production line undergoing qualification for intended use

Q Sepharose Big Beads

Published on: 12/16/2019 Change to packaging material for package size 40L and 60L

Q Sepharose Fast Flow

Published on: 12/16/2019 Change to packaging material for package size 40L and 60L

Q Sepharose XL

Published on: 12/16/2019 Change to packaging material for package size 40L and 60L

rProtein A Sepharose Fast Flow

Published on: 02/12/2020 Insourcing of rProtein A ligand manufacturing
Published on: 12/16/2019 Change to packaging material for package size 40L and 60L
Published on: 06/05/2018 Introduction of alternative chemical used as reducing agent for rProtein A ligand

S Sepharose Fast Flow

Published on: 12/16/2019 Change to packaging material for package size 40L and 60L

Sephadex LH-20

Published on: 09/07/2018	Removal of detergent in final wash for Sephadex LH-20
Sepharose 4 Fast Flow	
Published on: 12/16/2019	Change to packaging material for package size 40L and 60L
Source 15ETH	
Published on: 05/24/2018	Discontinuation of SOURCE 15ETH
Source 15S	
Published on: 12/16/2019	Change to packaging material for package size 40L and 60L
SOURCE 30Q	-
Published on: 12/16/2019	Change to packaging material for package size 40L and 60L
SP Sepharose Big Beads	-
Published on: 12/16/2019	Change to packaging material for package size 40L and 60L
SP Sepharose Fast Flow	-
Published on: 12/16/2019	Change to packaging material for package size 40L and 60L
SP Sepharose High Performance	-
Published on: 12/16/2019	Change to packaging material for package size 40L and 60L
SP Sepharose XL	-
Published on: 12/16/2019	Change to packaging material for package size 40L and 60L
Superdex 200 prep grade	-
Published on: 12/16/2019	Change to packaging material for package size 40L and 60L
VIIISelect	
Published on: 02/21/2019	Update on: New production line undergoing qualification for intended use
Published on: 04/10/2018	New production line undergoing qualification for intended use

Change Control Notification - Filtration

Global Notifications

Published on: 05/15/2020	Notification on Legal Entity changes
Published on: 05/14/2020	Final reminder for Notification on re-designed web page for Change Notifications and Regulatory Support Documentation
Published on: 05/11/2020	Reminder for Notification on re-designed web page for Change Notifications and Regulatory Support Documentation.
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Published on: 10/01/2019	Update to Pre-notification on new RS web page published 08 July 2019
Published on: 09/06/2019	Notification on Legal Entity changes - Correction
Published on: 08/30/2019	Notification on Legal Entity changes
Published on: 07/15/2019	Pre-notification on change of company name
Published on: 07/08/2019	Pre-notification new Regulatory Support web page
Published on: 07/06/2018	Update of GE Healthcare Life Sciences' Change Control Standard
Published on: 03/05/2018	Update of GE Healthcare Life Sciences' Change Control Standard

HF MaxCell Size 45, 65 and 85

Published on: 05/31/2019	190531HFWP-1_CCN_Change in Packaging for Hollow Fiber Cartridges
Published on: 03/27/2019	190327HFWM-1_Implementation of Automation Equipment for ReadyToProcess™ and standard Hollow Fiber Cartridges

HF MidGee and MidGee Hoop

Published on: 05/15/2020	200424HFWC-3_Implementation Notification_Change to Hollow Fiber BP Spec and CoQ for Cartridges with 0.2 Fiber
Published on: 05/15/2020	TW392538-W_CCN update new labels and certificate of quality
Published on: 04/27/2020	200424HFWC-2_Update_Change to Hollow Fiber BP Spec and CoQ for Cartridges with 0.2 (2-E & 2-G) Fiber
Published on: 04/24/2020	200424HFWC-1_Change to Hollow Fiber BP Spec and CoQ for Cartridges with 0.2 (2-E & 2-G) Fiber
Published on: 04/24/2020	200206HFWC-3_Implementation Notification_Change to Hollow Fiber BP Spec and CoQ for 0.45 (4E) fiber
Published on: 04/15/2020	2004015HFWM-1_Ultrafiltration Hollow Fiber Cartridge Air Diffusion Test Procedure and Equipment Updates
Published on: 04/10/2020	200206HFWC-2_Update_Change to Hollow Fiber BP Spec and CoQ for Cartridges with 0.45 (4-E) Fiber
Published on: 02/06/2020	200206HFWC-1_Change to Hollow Fiber Bubble Point Specification & CoQ for Cartridges Containing 0.45 (4-E) Fiber
Published on: 01/14/2020	Correction of Date_191220HFWM-2_Update_Qualification of Hollow Fiber spin line for the manufacture of 500-E fibers
Published on: 01/13/2020	191220HFWM-2_Update_Qualification of Hollow Fiber spin line for the manufacture of 500-E fibers
Published on: 12/20/2019	191220HFWM-1_Qualification of Hollow Fiber spin line for the manufacture of 500-E fibers
Published on: 12/20/2019	CCN Implementation Update_191112HFWC-1 Change to Hollow Fiber Bubble Point Specification and Certificate of Quality _20DEC2019

Published on: 11/13/2019

191112HFWC-1 Change to Hollow Fiber Bubble Point Specification and Certificate of Quality for Cartridges Containing 0.65 (6-D) Fiber

HF ProCell Size 152 and 154

Published on: 05/15/2020

200424HFWC-3_Implementation Notification_Change to Hollow Fiber BP Spec and CoQ for Cartridges with 0.2 Fiber

Published on: 05/15/2020

TW392538-W_CCN update new labels and certificate of quality

Published on: 04/27/2020

200424HFWC-2_Update_Change to Hollow Fiber BP Spec and CoQ for Cartridges with 0.2 (2-E & 2-G) Fiber

Published on: 04/24/2020

200424HFWC-1_Change to Hollow Fiber BP Spec and CoQ for Cartridges with 0.2 (2-E & 2-G) Fiber

Published on: 04/24/2020

200206HFWC-3_Implementation Notification_Change to Hollow Fiber BP Spec and CoQ for 0.45 (4E) fiber

Published on: 04/15/2020

2004015HFWM-1_Ultrafiltration Hollow Fiber Cartridge Air Diffusion Test Procedure and Equipment Updates

Published on: 04/10/2020

200206HFWC-2_Update_Change to Hollow Fiber BP Spec and CoQ for Cartridges with 0.45 (4-E) Fiber

Published on: 02/06/2020

200206HFWC-1_Change to Hollow Fiber Bubble Point Specification & CoQ for Cartridges Containing 0.45 (4-E) Fiber

Published on: 01/14/2020

Correction of Date_191220HFWM-2_Update_Qualification of Hollow Fiber spin line for the manufacture of 500-E fibers

Published on: 01/13/2020

191220HFWM-2_Update_Qualification of Hollow Fiber spin line for the manufacture of 500-E fibers

Published on: 12/20/2019

191220HFWM-1_Qualification of Hollow Fiber spin line for the manufacture of 500-E fibers

Published on: 12/20/2019

CCN Implementation Update_191112HFWC-1 Change to Hollow Fiber Bubble Point Specification and Certificate of Quality _20DEC2019

Published on: 11/13/2019

191112HFWC-1 Change to Hollow Fiber Bubble Point Specification and Certificate of Quality for Cartridges Containing 0.65 (6-D) Fiber

Published on: 05/31/2019

190531HFWP-1_CCN_Change in Packaging for Hollow Fiber Cartridges

HF Retrofit Size 55R and 75R

Published on: 05/15/2020

200424HFWC-3_Implementation Notification_Change to Hollow Fiber BP Spec and CoQ for Cartridges with 0.2 Fiber

Published on: 05/15/2020

TW392538-W_CCN update new labels and certificate of quality

Published on: 04/27/2020

200424HFWC-2_Update_Change to Hollow Fiber BP Spec and CoQ for Cartridges with 0.2 (2-E & 2-G) Fiber

Published on: 04/24/2020

200424HFWC-1_Change to Hollow Fiber BP Spec and CoQ for Cartridges with 0.2 (2-E & 2-G) Fiber

Published on: 04/24/2020

200206HFWC-3_Implementation Notification_Change to Hollow Fiber BP Spec and CoQ for 0.45 (4E) fiber

Published on: 04/15/2020

2004015HFWM-1_Ultrafiltration Hollow Fiber Cartridge Air Diffusion Test Procedure and Equipment Updates

Published on: 04/10/2020

200206HFWC-2_Update_Change to Hollow Fiber BP Spec and CoQ for Cartridges with 0.45 (4-E) Fiber

Published on: 02/06/2020

200206HFWC-1_Change to Hollow Fiber Bubble Point Specification & CoQ for Cartridges Containing 0.45 (4-E) Fiber

Published on: 01/14/2020

Correction of Date_191220HFWM-2_Update_Qualification of Hollow Fiber spin line for the manufacture of 500-E fibers

Published on: 01/13/2020

191220HFWM-2_Update_Qualification of Hollow Fiber spin line for the manufacture of 500-E fibers

Published on: 12/20/2019

191220HFWM-1_Qualification of Hollow Fiber spin line for the manufacture of 500-E fibers

Published on: 12/20/2019

CCN Implementation Update_191112HFWC-1 Change to Hollow Fiber Bubble Point Specification and Certificate of Quality _20DEC2019

Published on: 11/13/2019

191112HFWC-1 Change to Hollow Fiber Bubble Point Specification and Certificate of Quality for Cartridges Containing 0.65 (6-D) Fiber

Published on: 03/27/2019

190327HFWM-1_Implementation of Automation Equipment for ReadyToProcess™ and standard Hollow Fiber Cartridges

HF SIP Size 35SMO and 55SMO

Published on: 05/15/2020

200424HFWC-3_Implementation Notification_Change to Hollow Fiber BP Spec and CoQ for Cartridges with 0.2 Fiber

Published on: 05/15/2020	TW392538-W_CCN update new labels and certificate of quality
Published on: 04/27/2020	200424HFWC-2_Update_Change to Hollow Fiber BP Spec and CoQ for Cartridges with 0.2 (2-E & 2-G) Fiber
Published on: 04/24/2020	200424HFWC-1_Change to Hollow Fiber BP Spec and CoQ for Cartridges with 0.2 (2-E & 2-G) Fiber
Published on: 04/24/2020	200206HFWC-3_Implementation Notification_Change to Hollow Fiber BP Spec and CoQ for 0.45 (4E) fiber
Published on: 04/15/2020	2004015HFWM-1_Ultrafiltration Hollow Fiber Cartridge Air Diffusion Test Procedure and Equipment Updates
Published on: 04/10/2020	200206HFWC-2_Update_Change to Hollow Fiber BP Spec and CoQ for Cartridges with 0.45 (4-E) Fiber
Published on: 02/06/2020	200206HFWC-1_Change to Hollow Fiber Bubble Point Specification & CoQ for Cartridges Containing 0.45 (4-E) Fiber
Published on: 01/14/2020	Correction of Date_191220HFWM-2_Update_Qualification of Hollow Fiber spin line for the manufacture of 500-E fibers
Published on: 01/13/2020	191220HFWM-2_Update_Qualification of Hollow Fiber spin line for the manufacture of 500-E fibers
Published on: 12/20/2019	191220HFWM-1_Qualification of Hollow Fiber spin line for the manufacture of 500-E fibers
Published on: 12/20/2019	CCN Implementation Update_191112HFWC-1 Change to Hollow Fiber Bubble Point Specification and Certificate of Quality _20DEC2019
Published on: 11/13/2019	191112HFWC-1 Change to Hollow Fiber Bubble Point Specification and Certificate of Quality for Cartridges Containing 0.65 (6-D) Fiber

HF SIP Size 35STM and 55STM

Published on: 05/15/2020	200424HFWC-3_Implementation Notification_Change to Hollow Fiber BP Spec and CoQ for Cartridges with 0.2 Fiber
Published on: 05/15/2020	TW392538-W_CCN update new labels and certificate of quality
Published on: 04/27/2020	200424HFWC-2_Update_Change to Hollow Fiber BP Spec and CoQ for Cartridges with 0.2 (2-E & 2-G) Fiber
Published on: 04/24/2020	200424HFWC-1_Change to Hollow Fiber BP Spec and CoQ for Cartridges with 0.2 (2-E & 2-G) Fiber
Published on: 04/24/2020	200206HFWC-3_Implementation Notification_Change to Hollow Fiber BP Spec and CoQ for 0.45 (4E) fiber
Published on: 04/15/2020	2004015HFWM-1_Ultrafiltration Hollow Fiber Cartridge Air Diffusion Test Procedure and Equipment Updates
Published on: 04/10/2020	200206HFWC-2_Update_Change to Hollow Fiber BP Spec and CoQ for Cartridges with 0.45 (4-E) Fiber
Published on: 02/06/2020	200206HFWC-1_Change to Hollow Fiber Bubble Point Specification & CoQ for Cartridges Containing 0.45 (4-E) Fiber
Published on: 01/14/2020	Correction of Date_191220HFWM-2_Update_Qualification of Hollow Fiber spin line for the manufacture of 500-E fibers
Published on: 01/13/2020	191220HFWM-2_Update_Qualification of Hollow Fiber spin line for the manufacture of 500-E fibers
Published on: 12/20/2019	191220HFWM-1_Qualification of Hollow Fiber spin line for the manufacture of 500-E fibers
Published on: 12/20/2019	CCN Implementation Update_191112HFWC-1 Change to Hollow Fiber Bubble Point Specification and Certificate of Quality _20DEC2019
Published on: 11/13/2019	191112HFWC-1 Change to Hollow Fiber Bubble Point Specification and Certificate of Quality for Cartridges Containing 0.65 (6-D) Fiber

HF SIP Size 45MSM,65 MSM,85MSM

Published on: 05/15/2020	200424HFWC-3_Implementation Notification_Change to Hollow Fiber BP Spec and CoQ for Cartridges with 0.2 Fiber
Published on: 05/15/2020	TW392538-W_CCN update new labels and certificate of quality
Published on: 04/27/2020	200424HFWC-2_Update_Change to Hollow Fiber BP Spec and CoQ for Cartridges with 0.2 (2-E & 2-G) Fiber
Published on: 04/24/2020	200424HFWC-1_Change to Hollow Fiber BP Spec and CoQ for Cartridges with 0.2 (2-E & 2-G) Fiber
Published on: 04/24/2020	200206HFWC-3_Implementation Notification_Change to Hollow Fiber BP Spec and CoQ for 0.45 (4E) fiber
Published on: 04/15/2020	2004015HFWM-1_Ultrafiltration Hollow Fiber Cartridge Air Diffusion Test Procedure and Equipment Updates

Published on: 04/10/2020	200206HFWC-2_Update_Change to Hollow Fiber BP Spec and CoQ for Cartridges with 0.45 (4-E) Fiber
Published on: 02/06/2020	200206HFWC-1_Change to Hollow Fiber Bubble Point Specification & CoQ for Cartridges Containing 0.45 (4-E) Fiber
Published on: 01/14/2020	Correction of Date_191220HFWM-2_Update_Qualification of Hollow Fiber spin line for the manufacture of 500-E fibers
Published on: 01/13/2020	191220HFWM-2_Update_Qualification of Hollow Fiber spin line for the manufacture of 500-E fibers
Published on: 12/20/2019	191220HFWM-1_Qualification of Hollow Fiber spin line for the manufacture of 500-E fibers
Published on: 12/20/2019	CCN Implementation Update_191112HFWC-1 Change to Hollow Fiber Bubble Point Specification and Certificate of Quality _20DEC2019
Published on: 11/13/2019	191112HFWC-1 Change to Hollow Fiber Bubble Point Specification and Certificate of Quality for Cartridges Containing 0.65 (6-D) Fiber
Published on: 05/31/2019	190531HFWP-1_CCN_Change in Packaging for Hollow Fiber Cartridges
Published on: 03/27/2019	190327HFWM-1_Implementation of Automation Equipment for ReadyToProcess™ and standard Hollow Fiber Cartridges

Hollow Fiber Size 3 and 3X2

Published on: 05/15/2020	200424HFWC-3_Implementation Notification_Change to Hollow Fiber BP Spec and CoQ for Cartridges with 0.2 Fiber
Published on: 05/15/2020	TW392538-W_CCN update new labels and certificate of quality
Published on: 04/27/2020	200424HFWC-2_Update_Change to Hollow Fiber BP Spec and CoQ for Cartridges with 0.2 (2-E & 2-G) Fiber
Published on: 04/24/2020	200424HFWC-1_Change to Hollow Fiber BP Spec and CoQ for Cartridges with 0.2 (2-E & 2-G) Fiber
Published on: 04/24/2020	200206HFWC-3_Implementation Notification_Change to Hollow Fiber BP Spec and CoQ for 0.45 (4E) fiber
Published on: 04/15/2020	2004015HFWM-1_Ultrafiltration Hollow Fiber Cartridge Air Diffusion Test Procedure and Equipment Updates
Published on: 04/10/2020	200206HFWC-2_Update_Change to Hollow Fiber BP Spec and CoQ for Cartridges with 0.45 (4-E) Fiber
Published on: 02/06/2020	200206HFWC-1_Change to Hollow Fiber Bubble Point Specification & CoQ for Cartridges Containing 0.45 (4-E) Fiber
Published on: 01/14/2020	Correction of Date_191220HFWM-2_Update_Qualification of Hollow Fiber spin line for the manufacture of 500-E fibers
Published on: 01/13/2020	191220HFWM-2_Update_Qualification of Hollow Fiber spin line for the manufacture of 500-E fibers
Published on: 12/20/2019	191220HFWM-1_Qualification of Hollow Fiber spin line for the manufacture of 500-E fibers
Published on: 12/20/2019	CCN Implementation Update_191112HFWC-1 Change to Hollow Fiber Bubble Point Specification and Certificate of Quality _20DEC2019
Published on: 11/13/2019	191112HFWC-1 Change to Hollow Fiber Bubble Point Specification and Certificate of Quality for Cartridges Containing 0.65 (6-D) Fiber

Hollow Fiber Size 35, 55 and 75

Published on: 05/15/2020	200424HFWC-3_Implementation Notification_Change to Hollow Fiber BP Spec and CoQ for Cartridges with 0.2 Fiber
Published on: 05/15/2020	TW392538-W_CCN update new labels and certificate of quality
Published on: 04/27/2020	200424HFWC-2_Update_Change to Hollow Fiber BP Spec and CoQ for Cartridges with 0.2 (2-E & 2-G) Fiber
Published on: 04/24/2020	200424HFWC-1_Change to Hollow Fiber BP Spec and CoQ for Cartridges with 0.2 (2-E & 2-G) Fiber
Published on: 04/24/2020	200206HFWC-3_Implementation Notification_Change to Hollow Fiber BP Spec and CoQ for 0.45 (4E) fiber
Published on: 04/15/2020	2004015HFWM-1_Ultrafiltration Hollow Fiber Cartridge Air Diffusion Test Procedure and Equipment Updates
Published on: 04/10/2020	200206HFWC-2_Update_Change to Hollow Fiber BP Spec and CoQ for Cartridges with 0.45 (4-E) Fiber
Published on: 02/06/2020	200206HFWC-1_Change to Hollow Fiber Bubble Point Specification & CoQ for Cartridges Containing 0.45 (4-E) Fiber
Published on: 01/14/2020	Correction of Date_191220HFWM-2_Update_Qualification of Hollow Fiber spin line for the manufacture of 500-E fibers
Published on: 01/13/2020	191220HFWM-2_Update_Qualification of Hollow Fiber spin line for the manufacture of 500-E fibers

Published on: 12/20/2019
Published on: 12/20/2019
Published on: 11/13/2019
Published on: 03/27/2019

191220HFWM-1_Qualification of Hollow Fiber spin line for the manufacture of 500-E fibers
CCN Implementation Update_191112HFWC-1 Change to Hollow Fiber Bubble Point Specification and Certificate of Quality _20DEC2019
191112HFWC-1 Change to Hollow Fiber Bubble Point Specification and Certificate of Quality for Cartridges Containing 0.65 (6-D) Fiber
190327HFWM-1_Implementation of Automation Equipment for ReadyToProcess™ and standard Hollow Fiber Cartridges

Hollow Fiber Size 4 and 4X2

Published on: 05/15/2020
Published on: 05/15/2020
Published on: 04/27/2020
Published on: 04/24/2020
Published on: 04/15/2020
Published on: 04/10/2020
Published on: 02/06/2020
Published on: 01/14/2020
Published on: 01/13/2020
Published on: 12/20/2019
Published on: 12/20/2019
Published on: 11/13/2019
Published on: 12/20/2018

200424HFWC-3_Implementation Notification_Change to Hollow Fiber BP Spec and CoQ for Cartridges with 0.2 Fiber
TW392538-W_CCN update new labels and certificate of quality
200424HFWC-2_Update_Change to Hollow Fiber BP Spec and CoQ for Cartridges with 0.2 (2-E & 2-G) Fiber
200424HFWC-1_Change to Hollow Fiber BP Spec and CoQ for Cartridges with 0.2 (2-E & 2-G) Fiber
200206HFWC-3_Implementation Notification_Change to Hollow Fiber BP Spec and CoQ for 0.45 (4E) fiber
2004015HFWM-1_Ultrafiltration Hollow Fiber Cartridge Air Diffusion Test Procedure and Equipment Updates
200206HFWC-2_Update_Change to Hollow Fiber BP Spec and CoQ for Cartridges with 0.45 (4-E) Fiber
200206HFWC-1_Change to Hollow Fiber Bubble Point Specification & CoQ for Cartridges Containing 0.45 (4-E) Fiber
Correction of Date_191220HFWM-2_Update_Qualification of Hollow Fiber spin line for the manufacture of 500-E fibers
191220HFWM-2_Update_Qualification of Hollow Fiber spin line for the manufacture of 500-E fibers
191220HFWM-1_Qualification of Hollow Fiber spin line for the manufacture of 500-E fibers
CCN Implementation Update_191112HFWC-1 Change to Hollow Fiber Bubble Point Specification and Certificate of Quality _20DEC2019
191112HFWC-1 Change to Hollow Fiber Bubble Point Specification and Certificate of Quality for Cartridges Containing 0.65 (6-D) Fiber
181220HFWF-1_HF_CCN

Hollow Fiber Size 5 and 6

Published on: 05/15/2020
Published on: 05/15/2020
Published on: 04/27/2020
Published on: 04/24/2020
Published on: 04/24/2020
Published on: 04/15/2020
Published on: 04/10/2020
Published on: 02/06/2020
Published on: 01/14/2020
Published on: 01/13/2020
Published on: 12/20/2019
Published on: 12/20/2019
Published on: 11/13/2019

200424HFWC-3_Implementation Notification_Change to Hollow Fiber BP Spec and CoQ for Cartridges with 0.2 Fiber
TW392538-W_CCN update new labels and certificate of quality
200424HFWC-2_Update_Change to Hollow Fiber BP Spec and CoQ for Cartridges with 0.2 (2-E & 2-G) Fiber
200424HFWC-1_Change to Hollow Fiber BP Spec and CoQ for Cartridges with 0.2 (2-E & 2-G) Fiber
200206HFWC-3_Implementation Notification_Change to Hollow Fiber BP Spec and CoQ for 0.45 (4E) fiber
2004015HFWM-1_Ultrafiltration Hollow Fiber Cartridge Air Diffusion Test Procedure and Equipment Updates
200206HFWC-2_Update_Change to Hollow Fiber BP Spec and CoQ for Cartridges with 0.45 (4-E) Fiber
200206HFWC-1_Change to Hollow Fiber Bubble Point Specification & CoQ for Cartridges Containing 0.45 (4-E) Fiber
Correction of Date_191220HFWM-2_Update_Qualification of Hollow Fiber spin line for the manufacture of 500-E fibers
191220HFWM-2_Update_Qualification of Hollow Fiber spin line for the manufacture of 500-E fibers
191220HFWM-1_Qualification of Hollow Fiber spin line for the manufacture of 500-E fibers
CCN Implementation Update_191112HFWC-1 Change to Hollow Fiber Bubble Point Specification and Certificate of Quality _20DEC2019
191112HFWC-1 Change to Hollow Fiber Bubble Point Specification and Certificate of Quality for Cartridges Containing 0.65 (6-D) Fiber

Hollow Fiber Size 8, 9 and 8SIP

Published on: 05/15/2020	200424HFWC-3_Implementation Notification_Change to Hollow Fiber BP Spec and CoQ for Cartridges with 0.2 Fiber
Published on: 05/15/2020	TW392538-W_CCN update new labels and certificate of quality
Published on: 04/27/2020	200424HFWC-2_Update_Change to Hollow Fiber BP Spec and CoQ for Cartridges with 0.2 (2-E & 2-G) Fiber
Published on: 04/24/2020	200424HFWC-1_Change to Hollow Fiber BP Spec and CoQ for Cartridges with 0.2 (2-E & 2-G) Fiber
Published on: 04/24/2020	200206HFWC-3_Implementation Notification_Change to Hollow Fiber BP Spec and CoQ for 0.45 (4E) fiber
Published on: 04/15/2020	2004015HFWM-1_Ultrafiltration Hollow Fiber Cartridge Air Diffusion Test Procedure and Equipment Updates
Published on: 04/10/2020	200206HFWC-2_Update_Change to Hollow Fiber BP Spec and CoQ for Cartridges with 0.45 (4-E) Fiber
Published on: 02/06/2020	200206HFWC-1_Change to Hollow Fiber Bubble Point Specification & CoQ for Cartridges Containing 0.45 (4-E) Fiber
Published on: 01/14/2020	Correction of Date_191220HFWM-2_Update_Qualification of Hollow Fiber spin line for the manufacture of 500-E fibers
Published on: 01/13/2020	191220HFWM-2_Update_Qualification of Hollow Fiber spin line for the manufacture of 500-E fibers
Published on: 12/20/2019	191220HFWM-1_Qualification of Hollow Fiber spin line for the manufacture of 500-E fibers
Published on: 12/20/2019	CCN Implementation Update_191112HFWC-1 Change to Hollow Fiber Bubble Point Specification and Certificate of Quality _20DEC2019
Published on: 11/13/2019	191112HFWC-1 Change to Hollow Fiber Bubble Point Specification and Certificate of Quality for Cartridges Containing 0.65 (6-D) Fiber

Hollow Fiber Start AXM and AXH

Published on: 05/15/2020	200424HFWC-3_Implementation Notification_Change to Hollow Fiber BP Spec and CoQ for Cartridges with 0.2 Fiber
Published on: 05/15/2020	TW392538-W_CCN update new labels and certificate of quality
Published on: 04/27/2020	200424HFWC-2_Update_Change to Hollow Fiber BP Spec and CoQ for Cartridges with 0.2 (2-E & 2-G) Fiber
Published on: 04/24/2020	200424HFWC-1_Change to Hollow Fiber BP Spec and CoQ for Cartridges with 0.2 (2-E & 2-G) Fiber
Published on: 04/24/2020	200206HFWC-3_Implementation Notification_Change to Hollow Fiber BP Spec and CoQ for 0.45 (4E) fiber
Published on: 04/15/2020	2004015HFWM-1_Ultrafiltration Hollow Fiber Cartridge Air Diffusion Test Procedure and Equipment Updates
Published on: 04/10/2020	200206HFWC-2_Update_Change to Hollow Fiber BP Spec and CoQ for Cartridges with 0.45 (4-E) Fiber
Published on: 02/06/2020	200206HFWC-1_Change to Hollow Fiber Bubble Point Specification & CoQ for Cartridges Containing 0.45 (4-E) Fiber
Published on: 01/14/2020	Correction of Date_191220HFWM-2_Update_Qualification of Hollow Fiber spin line for the manufacture of 500-E fibers
Published on: 01/13/2020	191220HFWM-2_Update_Qualification of Hollow Fiber spin line for the manufacture of 500-E fibers
Published on: 12/20/2019	191220HFWM-1_Qualification of Hollow Fiber spin line for the manufacture of 500-E fibers
Published on: 12/20/2019	CCN Implementation Update_191112HFWC-1 Change to Hollow Fiber Bubble Point Specification and Certificate of Quality _20DEC2019
Published on: 11/13/2019	191112HFWC-1 Change to Hollow Fiber Bubble Point Specification and Certificate of Quality for Cartridges Containing 0.65 (6-D) Fiber

Hollow Fiber VirA_Gard

Published on: 05/15/2020	200424HFWC-3_Implementation Notification_Change to Hollow Fiber BP Spec and CoQ for Cartridges with 0.2 Fiber
Published on: 05/15/2020	TW392538-W_CCN update new labels and certificate of quality
Published on: 04/27/2020	200424HFWC-2_Update_Change to Hollow Fiber BP Spec and CoQ for Cartridges with 0.2 (2-E & 2-G) Fiber
Published on: 04/24/2020	200424HFWC-1_Change to Hollow Fiber BP Spec and CoQ for Cartridges with 0.2 (2-E & 2-G) Fiber

Published on: 04/24/2020	200206HFWC-3_Implementation Notification_Change to Hollow Fiber BP Spec and CoQ for 0.45 (4E) fiber
Published on: 04/15/2020	2004015HFWM-1_Ultrafiltration Hollow Fiber Cartridge Air Diffusion Test Procedure and Equipment Updates
Published on: 04/10/2020	200206HFWC-2_Update_Change to Hollow Fiber BP Spec and CoQ for Cartridges with 0.45 (4-E) Fiber
Published on: 02/06/2020	200206HFWC-1_Change to Hollow Fiber Bubble Point Specification & CoQ for Cartridges Containing 0.45 (4-E) Fiber

Change Control Notification - Hyclone

Global Notifications

Published on: 05/15/2020	Notification on Legal Entity changes
Published on: 05/14/2020	Final reminder for Notification on re-designed web page for Change Notifications and Regulatory Support Documentation
Published on: 05/11/2020	Reminder for Notification on re-designed web page for Change Notifications and Regulatory Support Documentation.
Published on: 04/27/2020	Update on Notification on re-designed web page for Change Notifications and Regulatory Support Documentation.
Published on: 04/09/2020	Administrative update of standard for the change control process for designated products
Published on: 04/01/2020	Notification on change of company name
Published on: 03/20/2020	Notification on Legal Entity changes
Published on: 12/20/2019	Correction to notification regarding Legal entity changes for China
Published on: 11/29/2019	Notification on Legal Entity changes for Russia, China and India
Published on: 10/14/2019	Notification on Company Brand name and Legal Entity changes
Published on: 10/01/2019	Update to Pre-notification on new RS web page published 08 July 2019
Published on: 09/06/2019	Notification on Legal Entity changes - Correction
Published on: 08/30/2019	Notification on Legal Entity changes
Published on: 07/15/2019	Pre-notification on change of company name
Published on: 07/08/2019	Pre-notification new Regulatory Support web page
Published on: 11/16/2018	Global manufacturing of animal derived component free Cell Culture Powder Media CCN 181116CMLR-1
Published on: 07/06/2018	Update of GE Healthcare Life Sciences' Change Control Standard
Published on: 04/30/2018	HyClone Change from Bar Codes to a Quick Response Code (QR Code) on Product Labels: CCN: 180430XUWO-1
Published on: 03/05/2018	Update of GE Healthcare Life Sciences' Change Control Standard

Buffers & Process Liquids: Balanced salts

Published on: 12/18/2019	Addition of Manufacturing Site for L-Histidine Monohydrochloride Monohydrate SV10026, a Raw Material Used in HyClone Cell Culture Products CCN 3
Published on: 12/18/2019	Addition of Manufacturing Site for L-Histidine SV10025, a Raw Material Used in HyClone Cell Culture Products CCN 393746a
Published on: 06/22/2018	Additional Supplier for Raw Material d-Biotin CCN 180623CMLR-1
Published on: 06/22/2018	Additional Supplier for Raw Material Strontium Chloride Hexahydrate-CCN 180622CMMR-1

Buffers & Process Liquids: Buffers

Published on: 12/18/2019
Published on: 12/18/2019
Published on: 06/22/2018
Published on: 06/22/2018

Addition of Manufacturing Site for L-Histidine Monohydrochloride Monohydrate SV10026, a Raw Material Used in HyClone Cell Culture Products CCN 3
Addition of Manufacturing Site for L-Histidine SV10025, a Raw Material Used in HyClone Cell Culture Products CCN 393746a
Additional Supplier for Raw Material d-Biotin CCN 180623CMLR-1
Additional Supplier for Raw Material Strontium Chloride Hexahydrate-CCN 180622CMMR-1

Buffers & Process Liquids: Process Water

Published on: 04/24/2020
Published on: 04/05/2019
Published on: 03/22/2019

Rapid Sterility Test CCN 19-CC-069
18-CC-112 Additional 15-30°C Storage of HyClone Cell Culture Products
18-CC-118 Addition of Particulate Matter Testing as release criterion for Cell Culture WFI Quality Water, CH30154.XX

Medium: CHO Platform Medium

Published on: 03/02/2020
Published on: 02/28/2020
Published on: 12/20/2019
Published on: 12/18/2019
Published on: 12/18/2019
Published on: 09/27/2019
Published on: 06/03/2019
Published on: 04/12/2019
Published on: 02/20/2019
Published on: 11/16/2018
Published on: 11/02/2018
Published on: 10/26/2018
Published on: 08/20/2018
Published on: 06/22/2018
Published on: 06/22/2018
Published on: 06/18/2018
Published on: 05/14/2018

Update to Qualification of additional sources of amino acids for HyClone cell culture products CCN 403925
Qualification of additional sources of amino acids for HyClone cell culture products CCN 403925
Manufacturing Process Change for CDM4PerMAb CCN 397025
Addition of Manufacturing Site for L-Histidine Monohydrochloride Monohydrate SV10026, a Raw Material Used in HyClone Cell Culture Products CCN 3
Addition of Manufacturing Site for L-Histidine SV10025, a Raw Material Used in HyClone Cell Culture Products CCN 393746a
Extended shelf life for Select HyClone Cell Culture Powdered Media CCN 19-CC-051
Cease Current Milling Hold Out of Vitamin B12 and Poloxamer CCN 19-CC-042
Addition of Cell Culture Testing Lab in Singapore CCN 18-CC-042
Additional supplier of D-Galactose CCN 190220CMLR-1
Global manufacturing of animal derived component free Cell Culture Powder Media CCN 181116CMLR-1
181102CMLR-1: Additional Supplier for Raw Material Ethanolamine
181026CMLP-1: Implementation of twist ties in HyClone Cell Culture powder secondary packaging
Manufacturing Process Change for HyClone SFM4CHO Products CCN:180820CMMM-1
Additional Supplier for Raw Material d-Biotin CCN 180623CMLR-1
Additional Supplier for Raw Material Strontium Chloride Hexahydrate-CCN 180622CMMR-1
HyClone CCN 180615CMLP-1 Use of Twist Ties on DPM Outer Packaging
Update to change notification 16-CC-072c (originally sent 11 November 2016): Manufacturing capacity expansion of Pasching facility cell culture media

Medium: Classical Dry Powder Medium

Published on: 03/02/2020
Published on: 02/28/2020
Published on: 12/18/2019
Published on: 12/18/2019
Published on: 06/03/2019
Published on: 04/12/2019

Update to Qualification of additional sources of amino acids for HyClone cell culture products CCN 403925
Qualification of additional sources of amino acids for HyClone cell culture products CCN 403925
Addition of Manufacturing Site for L-Histidine Monohydrochloride Monohydrate SV10026, a Raw Material Used in HyClone Cell Culture Products CCN 3
Addition of Manufacturing Site for L-Histidine SV10025, a Raw Material Used in HyClone Cell Culture Products CCN 393746a
Cease Current Milling Hold Out of Vitamin B12 and Poloxamer CCN 19-CC-042
Addition of Cell Culture Testing Lab in Singapore CCN 18-CC-042

Published on: 02/20/2019
Published on: 11/16/2018
Published on: 10/26/2018
Published on: 06/22/2018
Published on: 06/22/2018
Published on: 06/18/2018
Published on: 05/14/2018

Additional supplier of D-Galactose CCN 190220CMLR-1
Global manufacturing of animal derived component free Cell Culture Powder Media CCN 181116CMLR-1
181026CMLP-1: Implementation of twist ties in HyClone Cell Culture powder secondary packaging
Additional Supplier for Raw Material d-Biotin CCN 180623CMLR-1
Additional Supplier for Raw Material Strontium Chloride Hexahydrate-CCN 180622CMMR-1
HyClone CCN 180615CMLP-1 Use of Twist Ties on DPM Outer Packaging
Update to change notification 16-CC-072c (originally sent 11 November 2016): Manufacturing capacity expansion of Pasching facility cell culture media

Medium: Classical Liquid Medium

Published on: 03/02/2020
Published on: 02/28/2020
Published on: 12/18/2019
Published on: 12/18/2019
Published on: 06/03/2019
Published on: 02/20/2019
Published on: 06/22/2018
Published on: 06/22/2018

Update to Qualification of additional sources of amino acids for HyClone cell culture products CCN 403925
Qualification of additional sources of amino acids for HyClone cell culture products CCN 403925
Addition of Manufacturing Site for L-Histidine Monohydrochloride Monohydrate SV10026, a Raw Material Used in HyClone Cell Culture Products CCN 3
Addition of Manufacturing Site for L-Histidine SV10025, a Raw Material Used in HyClone Cell Culture Products CCN 393746a
Cease Current Milling Hold Out of Vitamin B12 and Poloxamer CCN 19-CC-042
Additional supplier of D-Galactose CCN 190220CMLR-1
Additional Supplier for Raw Material d-Biotin CCN 180623CMLR-1
Additional Supplier for Raw Material Strontium Chloride Hexahydrate-CCN 180622CMMR-1

Medium: HEK293 and PERC6

Published on: 03/02/2020
Published on: 02/28/2020
Published on: 12/20/2019
Published on: 12/18/2019
Published on: 12/18/2019
Published on: 06/03/2019
Published on: 04/12/2019
Published on: 11/16/2018
Published on: 11/02/2018
Published on: 10/26/2018
Published on: 06/22/2018
Published on: 06/22/2018
Published on: 06/18/2018
Published on: 05/14/2018
Published on: 04/06/2018

Update to Qualification of additional sources of amino acids for HyClone cell culture products CCN 403925
Qualification of additional sources of amino acids for HyClone cell culture products CCN 403925
Add Ability to Perform Amino Acid Analysis in House for Items Manufactured in Pasching Austria CCN 19-CC-039
Addition of Manufacturing Site for L-Histidine Monohydrochloride Monohydrate SV10026, a Raw Material Used in HyClone Cell Culture Products CCN 3
Addition of Manufacturing Site for L-Histidine SV10025, a Raw Material Used in HyClone Cell Culture Products CCN 393746a
Cease Current Milling Hold Out of Vitamin B12 and Poloxamer CCN 19-CC-042
Addition of Cell Culture Testing Lab in Singapore CCN 18-CC-042
Global manufacturing of animal derived component free Cell Culture Powder Media CCN 181116CMLR-1
181102CMLR-1: Additional Supplier for Raw Material Ethanolamine
181026CMLP-1: Implementation of twist ties in HyClone Cell Culture powder secondary packaging
Additional Supplier for Raw Material d-Biotin CCN 180623CMLR-1
Additional Supplier for Raw Material Strontium Chloride Hexahydrate-CCN 180622CMMR-1
HyClone CCN 180615CMLP-1 Use of Twist Ties on DPM Outer Packaging
Update to change notification 16-CC-072c (originally sent 11 November 2016): Manufacturing capacity expansion of Pasching facility cell culture media
Expiry Date extension for HyCell TransFx-H

Medium: Hybridoma and Myeloma

Published on: 03/02/2020
Published on: 02/28/2020
Published on: 12/18/2019
Published on: 12/18/2019
Published on: 06/03/2019
Published on: 04/12/2019
Published on: 02/20/2019
Published on: 11/16/2018
Published on: 11/02/2018
Published on: 10/26/2018
Published on: 06/22/2018
Published on: 06/22/2018
Published on: 06/18/2018
Published on: 05/14/2018

Update to Qualification of additional sources of amino acids for HyClone cell culture products CCN 403925
Qualification of additional sources of amino acids for HyClone cell culture products CCN 403925
Addition of Manufacturing Site for L-Histidine Monohydrochloride Monohydrate SV10026, a Raw Material Used in HyClone Cell Culture Products CCN 3
Addition of Manufacturing Site for L-Histidine SV10025, a Raw Material Used in HyClone Cell Culture Products CCN 393746a
Cease Current Milling Hold Out of Vitamin B12 and Poloxamer CCN 19-CC-042
Addition of Cell Culture Testing Lab in Singapore CCN 18-CC-042
Additional supplier of D-Galactose CCN 190220CMLR-1
Global manufacturing of animal derived component free Cell Culture Powder Media CCN 181116CMLR-1
181102CMLR-1: Additional Supplier for Raw Material Ethanolamine
181026CMLP-1: Implementation of twist ties in HyClone Cell Culture powder secondary packaging
Additional Supplier for Raw Material d-Biotin CCN 180623CMLR-1
Additional Supplier for Raw Material Strontium Chloride Hexahydrate-CCN 180622CMMR-1
HyClone CCN 180615CMLP-1 Use of Twist Ties on DPM Outer Packaging
Update to change notification 16-CC-072c (originally sent 11 November 2016): Manufacturing capacity expansion of Pasching facility cell culture media

Medium: Insect Cell Culture Medium

Published on: 03/02/2020
Published on: 02/28/2020
Published on: 12/18/2019
Published on: 12/18/2019
Published on: 06/03/2019
Published on: 04/12/2019
Published on: 11/16/2018
Published on: 11/02/2018
Published on: 10/26/2018
Published on: 06/22/2018
Published on: 06/22/2018
Published on: 06/18/2018
Published on: 05/14/2018

Update to Qualification of additional sources of amino acids for HyClone cell culture products CCN 403925
Qualification of additional sources of amino acids for HyClone cell culture products CCN 403925
Addition of Manufacturing Site for L-Histidine Monohydrochloride Monohydrate SV10026, a Raw Material Used in HyClone Cell Culture Products CCN 3
Addition of Manufacturing Site for L-Histidine SV10025, a Raw Material Used in HyClone Cell Culture Products CCN 393746a
Cease Current Milling Hold Out of Vitamin B12 and Poloxamer CCN 19-CC-042
Addition of Cell Culture Testing Lab in Singapore CCN 18-CC-042
Global manufacturing of animal derived component free Cell Culture Powder Media CCN 181116CMLR-1
181102CMLR-1: Additional Supplier for Raw Material Ethanolamine
181026CMLP-1: Implementation of twist ties in HyClone Cell Culture powder secondary packaging
Additional Supplier for Raw Material d-Biotin CCN 180623CMLR-1
Additional Supplier for Raw Material Strontium Chloride Hexahydrate-CCN 180622CMMR-1
HyClone CCN 180615CMLP-1 Use of Twist Ties on DPM Outer Packaging
Update to change notification 16-CC-072c (originally sent 11 November 2016): Manufacturing capacity expansion of Pasching facility cell culture media

Medium: Stem Cell Culture Medium

Published on: 03/02/2020
Published on: 02/28/2020
Published on: 12/18/2019
Published on: 12/18/2019
Published on: 06/03/2019

Update to Qualification of additional sources of amino acids for HyClone cell culture products CCN 403925
Qualification of additional sources of amino acids for HyClone cell culture products CCN 403925
Addition of Manufacturing Site for L-Histidine Monohydrochloride Monohydrate SV10026, a Raw Material Used in HyClone Cell Culture Products CCN 3
Addition of Manufacturing Site for L-Histidine SV10025, a Raw Material Used in HyClone Cell Culture Products CCN 393746a
Cease Current Milling Hold Out of Vitamin B12 and Poloxamer CCN 19-CC-042

Published on: 04/12/2019	Addition of Cell Culture Testing Lab in Singapore CCN 18-CC-042
Published on: 02/20/2019	Additional supplier of D-Galactose CCN 190220CMLR-1
Published on: 11/16/2018	Global manufacturing of animal derived component free Cell Culture Powder Media CCN 181116CMLR-1
Published on: 11/02/2018	181102CMLR-1: Additional Supplier for Raw Material Ethanolamine
Published on: 10/26/2018	181026CMLP-1: Implementation of twist ties in HyClone Cell Culture powder secondary packaging
Published on: 06/22/2018	Additional Supplier for Raw Material d-Biotin CCN 180623CMLR-1
Published on: 06/22/2018	Additional Supplier for Raw Material Strontium Chloride Hexahydrate-CCN 180622CMMR-1
Published on: 06/18/2018	HyClone CCN 180615CMLP-1 Use of Twist Ties on DPM Outer Packaging
Published on: 05/14/2018	Update to change notification 16-CC-072c (originally sent 11 November 2016): Manufacturing capacity expansion of Pasching facility cell culture media

Medium: Viral Vaccine Platform Medium

Published on: 03/02/2020	Update to Qualification of additional sources of amino acids for HyClone cell culture products CCN 403925
Published on: 02/28/2020	Qualification of additional sources of amino acids for HyClone cell culture products CCN 403925
Published on: 12/18/2019	Addition of Manufacturing Site for L-Histidine Monohydrochloride Monohydrate SV10026, a Raw Material Used in HyClone Cell Culture Products CCN 3
Published on: 12/18/2019	Addition of Manufacturing Site for L-Histidine SV10025, a Raw Material Used in HyClone Cell Culture Products CCN 393746a
Published on: 09/27/2019	Extended shelf life for Select Hyclone Cell Culture Powdered Media CCN 19-CC-051
Published on: 06/03/2019	Cease Current Milling Hold Out of Vitamin B12 and Poloxamer CCN 19-CC-042
Published on: 04/12/2019	Addition of Cell Culture Testing Lab in Singapore CCN 18-CC-042
Published on: 02/20/2019	Additional supplier of D-Galactose CCN 190220CMLR-1
Published on: 11/16/2018	Global manufacturing of animal derived component free Cell Culture Powder Media CCN 181116CMLR-1
Published on: 11/02/2018	181102CMLR-1: Additional Supplier for Raw Material Ethanolamine
Published on: 10/26/2018	181026CMLP-1: Implementation of twist ties in HyClone Cell Culture powder secondary packaging
Published on: 06/22/2018	Additional Supplier for Raw Material d-Biotin CCN 180623CMLR-1
Published on: 06/22/2018	Additional Supplier for Raw Material Strontium Chloride Hexahydrate-CCN 180622CMMR-1
Published on: 06/18/2018	HyClone CCN 180615CMLP-1 Use of Twist Ties on DPM Outer Packaging
Published on: 05/14/2018	Update to change notification 16-CC-072c (originally sent 11 November 2016): Manufacturing capacity expansion of Pasching facility cell culture media

Reagents & Supplements: Antibiotics & Selection Agents

Published on: 12/18/2019	Addition of Manufacturing Site for L-Histidine Monohydrochloride Monohydrate SV10026, a Raw Material Used in HyClone Cell Culture Products CCN 3
Published on: 12/18/2019	Addition of Manufacturing Site for L-Histidine SV10025, a Raw Material Used in HyClone Cell Culture Products CCN 393746a
Published on: 11/16/2018	Global manufacturing of animal derived component free Cell Culture Powder Media CCN 181116CMLR-1
Published on: 06/22/2018	Additional Supplier for Raw Material d-Biotin CCN 180623CMLR-1
Published on: 06/22/2018	Additional Supplier for Raw Material Strontium Chloride Hexahydrate-CCN 180622CMMR-1

Reagents & Supplements: Cell Dissociation Reagents

Published on: 12/18/2019	Addition of Manufacturing Site for L-Histidine Monohydrochloride Monohydrate SV10026, a Raw Material Used in HyClone Cell Culture Products CCN 3
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Published on: 12/18/2019	Addition of Manufacturing Site for L-Histidine SV10025, a Raw Material Used in HyClone Cell Culture Products CCN 393746a
Published on: 06/22/2018	Additional Supplier for Raw Material d-Biotin CCN 180623CMLR-1
Published on: 06/22/2018	Additional Supplier for Raw Material Strontium Chloride Hexahydrate-CCN 180622CMMR-1

Reagents & Supplements: Cryopreservation Medium

Published on: 03/02/2020	Update to Qualification of additional sources of amino acids for HyClone cell culture products CCN 403925
Published on: 02/28/2020	Qualification of additional sources of amino acids for HyClone cell culture products CCN 403925
Published on: 12/18/2019	Addition of Manufacturing Site for L-Histidine Monohydrochloride Monohydrate SV10026, a Raw Material Used in HyClone Cell Culture Products CCN 3
Published on: 12/18/2019	Addition of Manufacturing Site for L-Histidine SV10025, a Raw Material Used in HyClone Cell Culture Products CCN 393746a
Published on: 06/22/2018	Additional Supplier for Raw Material d-Biotin CCN 180623CMLR-1
Published on: 06/22/2018	Additional Supplier for Raw Material Strontium Chloride Hexahydrate-CCN 180622CMMR-1

Reagents & Supplements: Medium Supplements

Published on: 03/02/2020	Update to Qualification of additional sources of amino acids for HyClone cell culture products CCN 403925
Published on: 02/28/2020	Qualification of additional sources of amino acids for HyClone cell culture products CCN 403925
Published on: 12/20/2019	Manufacturing Process Change for CDM4PerMAb CCN 397025
Published on: 12/18/2019	Addition of Manufacturing Site for L-Histidine Monohydrochloride Monohydrate SV10026, a Raw Material Used in HyClone Cell Culture Products CCN 3
Published on: 12/18/2019	Addition of Manufacturing Site for L-Histidine SV10025, a Raw Material Used in HyClone Cell Culture Products CCN 393746a
Published on: 09/27/2019	Extended shelf life for Select Hyclone Cell Culture Powdered Media CCN 19-CC-051
Published on: 11/16/2018	Global manufacturing of animal derived component free Cell Culture Powder Media CCN 181116CMLR-1
Published on: 11/02/2018	181102CMLR-1: Additional Supplier for Raw Material L-Lysine Monohydrate
Published on: 11/02/2018	181102CMLR-1: Additional Supplier for Raw Material Ethanolamine
Published on: 06/22/2018	Additional Supplier for Raw Material d-Biotin CCN 180623CMLR-1
Published on: 06/22/2018	Additional Supplier for Raw Material Strontium Chloride Hexahydrate-CCN 180622CMMR-1

Reagents & Supplements: Microcarriers

Published on: 06/22/2018	Additional Supplier for Raw Material d-Biotin CCN 180623CMLR-1
Published on: 06/22/2018	Additional Supplier for Raw Material Strontium Chloride Hexahydrate-CCN 180622CMMR-1

Serum: Calf Serum

Published on: 03/02/2020	Update to Qualification of additional sources of amino acids for HyClone cell culture products CCN 403925
Published on: 02/28/2020	Qualification of additional sources of amino acids for HyClone cell culture products CCN 403925
Published on: 05/03/2019	19-CC-012 Updated Serum CoA's and WID's to Current Testing Standards
Published on: 04/05/2019	19-CC-010 Harmonization of Catalog number format on AU and NZ Serum COAs
Published on: 03/15/2019	19-CC-014 Update Hemoglobin Test Method to USP Method
Published on: 06/22/2018	Additional Supplier for Raw Material d-Biotin CCN 180623CMLR-1

Published on: 06/22/2018 Additional Supplier for Raw Material Strontium Chloride Hexahydrate-CCN 180622CMMR-1

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Serum: EMA Testing

Published on: 05/03/2019 19-CC-012 Updated Serum CoA's and WID's to Current Testing Standards
Published on: 04/05/2019 19-CC-010 Harmonization of Catalog number format on AU and NZ Serum COAs
Published on: 06/22/2018 Additional Supplier for Raw Material d-Biotin CCN 180623CMLR-1
Published on: 06/22/2018 Additional Supplier for Raw Material Strontium Chloride Hexahydrate-CCN 180622CMMR-1

Serum: Fetal Bovine Serum (FBS)

Published on: 03/02/2020 Update to Qualification of additional sources of amino acids for HyClone cell culture products CCN 403925
Published on: 02/28/2020 Qualification of additional sources of amino acids for HyClone cell culture products CCN 403925
Published on: 05/03/2019 19-CC-012 Updated Serum CoA's and WID's to Current Testing Standards
Published on: 04/05/2019 19-CC-010 Harmonization of Catalog number format on AU and NZ Serum COAs
Published on: 06/22/2018 Additional Supplier for Raw Material d-Biotin CCN 180623CMLR-1
Published on: 06/22/2018 Additional Supplier for Raw Material Strontium Chloride Hexahydrate-CCN 180622CMMR-1

Serum: Fetal Bovine Serum (FBS) Alternatives

Published on: 03/02/2020 Update to Qualification of additional sources of amino acids for HyClone cell culture products CCN 403925
Published on: 02/28/2020 Qualification of additional sources of amino acids for HyClone cell culture products CCN 403925
Published on: 05/03/2019 19-CC-012 Updated Serum CoA's and WID's to Current Testing Standards
Published on: 04/05/2019 19-CC-010 Harmonization of Catalog number format on AU and NZ Serum COAs
Published on: 03/15/2019 19-CC-014 Update Hemoglobin Test Method to USP Method
Published on: 06/22/2018 Additional Supplier for Raw Material d-Biotin CCN 180623CMLR-1
Published on: 06/22/2018 Additional Supplier for Raw Material Strontium Chloride Hexahydrate-CCN 180622CMMR-1

Serum: Other Serum Sources

Published on: 05/03/2019 19-CC-012 Updated Serum CoA's and WID's to Current Testing Standards
Published on: 04/05/2019 19-CC-010 Harmonization of Catalog number format on AU and NZ Serum COAs
Published on: 06/22/2018 Additional Supplier for Raw Material d-Biotin CCN 180623CMLR-1
Published on: 06/22/2018 Additional Supplier for Raw Material Strontium Chloride Hexahydrate-CCN 180622CMMR-1

Serum: Specialty Serum

Published on: 03/02/2020 Update to Qualification of additional sources of amino acids for HyClone cell culture products CCN 403925
Published on: 02/28/2020 Qualification of additional sources of amino acids for HyClone cell culture products CCN 403925
Published on: 05/03/2019 19-CC-012 Updated Serum CoA's and WID's to Current Testing Standards
Published on: 11/02/2018 181102CMLR-1: Additional Supplier for Raw Material Ethanolamine
Published on: 06/22/2018 Additional Supplier for Raw Material d-Biotin CCN 180623CMLR-1

Published on: 06/22/2018

Additional Supplier for Raw Material Strontium Chloride Hexahydrate-CCN 180622CMMR-1

Change Control Notification - ReadyToProcess

Global Notifications

Published on: 05/15/2020

Notification on Legal Entity changes

Published on: 05/14/2020

Final reminder for Notification on re-designed web page for Change Notifications and Regulatory Support Documentation

Published on: 05/11/2020

Reminder for Notification on re-designed web page for Change Notifications and Regulatory Support Documentation.

Published on: 04/27/2020

Update on Notification on re-designed web page for Change Notifications and Regulatory Support Documentation.

Published on: 04/09/2020

Administrative update of standard for the change control process for designated products

Published on: 04/01/2020

Notification on change of company name

Published on: 03/26/2020

191227MXWS-02 - UPDATE Addition of supplier manufacturing sites for C-Flex® TPE tubing _R

Published on: 03/20/2020

Notification on Legal Entity changes

Published on: 12/27/2019

191227MXWS-01 - Addition of supplier manufacturing sites for C-Flex® TPE tubing_R

Published on: 12/20/2019

Correction to notification regarding Legal entity changes for China_CCN

Published on: 11/29/2019

Notification on Legal Entity changes for Russia, China and India

Published on: 10/14/2019

Notification on Company Brand name and Legal Entity changes

Published on: 10/01/2019

Update to Pre-notification on new RS web page published 08 July 2019

Published on: 09/06/2019

Notification on Legal Entity changes - Correction

Published on: 08/30/2019

Notification on Legal Entity changes

Published on: 07/15/2019

Pre-notification on change of company name

Published on: 07/08/2019

Pre-notification new Regulatory Support web page

Published on: 07/06/2018

Update of GE Healthcare Life Sciences' Change Control Standard

Published on: 05/28/2018

Update of label for chromatography resins and ReadyToProcess columns

Published on: 03/05/2018

Update of GE Healthcare Life Sciences' Change Control Standard

ÄKTA ready Flow Kit

Published on: 05/15/2020

TW392538-W_CCN update new labels and certificate of quality_encrypted

Published on: 04/03/2020

200403MXWM-1 Gamma irradiation dose range change

Published on: 03/20/2020

200320MXWO-0_GEHC LS Prenotification for Capacity Changes

Published on: 10/01/2019

ÄKTA™ ready Flow Kit Manufacturing and Materials of Construction Changes - Final Notification for Remaining Changes

Published on: 09/10/2019

190910MXWR-0: Pre-Notification of Replacement of TPE tubing in GE Healthcare Single-Use Assemblies

Published on: 08/22/2019

190822MXWO-1 - Alternate clamp qualified for use in ReadyToProcess™ assemblies

Published on: 06/21/2019

ÄKTA™ ready Flow Kit Manufacturing and Materials of Construction Changes – Final Notification for Bayonet Plugs and Flowmeter Housing Changes

Published on: 02/12/2019

Update: ÄKTA™ ready Flow Kit Manufacturing and Materials of Construction Changes, Additional Changes Included

Published on: 01/31/2019	180611RMWO-3_GEHC LS_ReadyMate_CCN
Published on: 01/16/2019	180611RMWO-2_GEHC LS_ReadyMate_CCN
Published on: 11/15/2018	180611RMWO-1_GEHC LS_ReadyMate_CCN
Published on: 07/16/2018	ÄKTA™ ready Flow Kit Manufacturing and Materials of Construction Changes
Published on: 06/12/2018	180611RMWO-0_GEHC LS_ReadyMate_Prenotification
Published on: 05/01/2018	ÄKTA™ ready Flow Kit packaging checklist modifications
Published on: 04/17/2018	Update: ÄKTA ready Flow Kit Y-Connector Redesign and Documentation Change
Published on: 04/17/2018	GEHC LS: Process Change for Westborough, MA Manufactured Single-Use Irradiated Products
Published on: 03/16/2018	Final Update: ÄKTA ready Gradient Flow Section Y-Connector Redesign and Documentation Change

ÄKTA ready XL

Published on: 05/15/2020	TW392538-W_CCN update new labels and certificate of quality_encrypted
Published on: 03/20/2020	200320MXWO-0_GEHC LS Prenotification for Capacity Changes
Published on: 11/15/2019	191115AKWR-1 - Material of construction change for flow meters used in ÄKTA™ ready XL flow kits

ÄKTA readyflux Flow Kit

Published on: 05/15/2020	TW392538-W_CCN update new labels and certificate of quality_encrypted
Published on: 04/03/2020	200403MXWM-1 Gamma irradiation dose range change
Published on: 04/02/2020	191219AXWF-2 - Update: Part Number updates for Conductivity Sensors used in ÄKTA™ readyflux flow kit
Published on: 03/20/2020	200320MXWO-0_GEHC LS Prenotification for Capacity Changes
Published on: 12/19/2019	191219AXWF-1 - Part Number updates for Conductivity Sensors used in ÄKTA™ readyflux flow kits
Published on: 08/22/2019	190822MXWO-1 - Alternate clamp qualified for use in ReadyToProcess™ assemblies
Published on: 03/12/2019	190228AXWO-2 Update to Product Documentation Packet for ÄKTA readyflux Flow Kits
Published on: 02/28/2019	190228AXWO-1 - Reduction in Shelf Life for the ÄKTA readyflux Flow Kit TC
Published on: 02/19/2019	190219AXWR-1: ÄKTA™ Readyflux Flow Kit Plus UV-Cell Gasket Material of Construction Change
Published on: 11/15/2018	180611RMWO-1_GEHC LS_ReadyMate_CCN
Published on: 06/12/2018	180611RMWO-0_GEHC LS_ReadyMate_Prenotification
Published on: 04/27/2018	Sterility validation and claim for ÄKTA™ readyflux Flow Kit RM (ReadyMate™ Disposable Aseptic Connectors) and Flow Kit Plus RM
Published on: 04/17/2018	GEHC LS: Process Change for Westborough, MA Manufactured Single-Use Irradiated Products

ReadyCircuit Bags

Published on: 05/15/2020	TW392538-W_CCN update new labels and certificate of quality_encrypted
Published on: 05/15/2020	200515MXWM-1 - Bag manufacturing process change and new equipment introduction for single-use products manufactured in Westborough, MA, US
Published on: 04/03/2020	200403MXWM-1 Gamma irradiation dose range change
Published on: 03/20/2020	200320MXWO-0_GEHC LS Prenotification for Capacity Changes
Published on: 10/28/2019	190913MXWO-2_ Pinch Clamp UPDATE

Published on: 09/13/2019	Pinch Clamp Change Control Notification__190913MXWO-1
Published on: 09/10/2019	190910MXWR-0: Pre-Notification of Replacement of TPE tubing in GE Healthcare Single-Use Assemblies
Published on: 08/22/2019	190822MXWO-1 - Alternate clamp qualified for use in ReadyToProcess™ assemblies
Published on: 08/13/2019	190813RCWC-1 - Revision to Certificate of Quality for ReadyCircuit™ Assembly
Published on: 08/22/2019	190822MXWO-1 - Alternate clamp qualified for use in ReadyToProcess™ assemblies
Published on: 01/31/2019	180611RMWO-3_GEHC LS_ReadyMate_CCN
Published on: 01/16/2019	180611RMWO-2_GEHC LS_ReadyMate_CCN
Published on: 11/15/2018	180611RMWO-1_GEHC LS_ReadyMate_CCN
Published on: 06/12/2018	180611RMWO-0_GEHC LS_ReadyMate_Prenotification
Published on: 04/17/2018	GEHC LS: Process Change for Westborough, MA Manufactured Single-Use Irradiated Products
Published on: 04/03/2018	Changes to the Certificate of Quality for the ReadyCircuit assembly

ReadyCircuit Bags China

Published on: 03/20/2020	200320MXWO-0_GEHC LS Prenotification for Capacity Changes
Published on: 03/02/2020	200302MXSM-1 - Process change to include the use of both layers of bag film for China manufactured Cellbag™ Bioreactor bags and ReadyCircuit™ Bag
Published on: 01/24/2020	200124MXSO-1 Pinch Clamp Change for China ReadyCircuit assemblies
Published on: 12/20/2019	191220MXSR-1_CCN_Component changes to Cellbag Bioreactor bags with Fortem film, China, and ReadyCircuit Assemblies, China
Published on: 07/12/2019	190712MXSC-1 GEHC LS Certificate Update for China Manufactured WAVE and ReadyToProcess Bags

ReadyCircuit NFF Assemblies

Published on: 05/15/2020	TW392538-W_CCN update new labels and certificate of quality_encrypted
Published on: 04/03/2020	200403MXWM-1 Gamma irradiation dose range change
Published on: 03/20/2020	200320MXWO-0_GEHC LS Prenotification for Capacity Changes
Published on: 10/28/2019	190913MXWO-2_ Pinch Clamp UPDATE
Published on: 09/13/2019	Pinch Clamp Change Control Notification__190913MXWO-1
Published on: 09/10/2019	190910MXWR-0: Pre-Notification of Replacement of TPE tubing in GE Healthcare Single-Use Assemblies
Published on: 08/22/2019	190822MXWO-1 - Alternate clamp qualified for use in ReadyToProcess™ assemblies
Published on: 08/13/2019	190813RCWC-1 - Revision to Certificate of Quality for ReadyCircuit™ Assembly
Published on: 01/31/2019	180611RMWO-3_GEHC LS_ReadyMate_CCN
Published on: 01/16/2019	180611RMWO-2_GEHC LS_ReadyMate_CCN
Published on: 12/20/2018	181012RFWM-2_UPDATE of Addition of Alternate Post-Manufacturing Equipment used for ReadyToProcess™ Hollow Fiber Cartridges
Published on: 11/15/2018	180611RMWO-1_GEHC LS_ReadyMate_CCN
Published on: 10/12/2018	181012RFWM-1: Addition of Alternate Post-Manufacturing Equipment used for ReadyToProcess™ Hollow Fiber Cartridges
Published on: 10/12/2018	181012RFWS-1: Change of Manufacturing Site for Component in ReadyToProcess™ Hollow Fiber Cartridges
Published on: 06/12/2018	180611RMWO-0_GEHC LS_ReadyMate_Prenotification
Published on: 04/17/2018	GEHC LS: Process Change for Westborough, MA Manufactured Single-Use Irradiated Products

Published on: 04/03/2018 Changes to the Certificate of Quality for the ReadyCircuit assembly

ReadyCircuit Sensor Assemblies

Published on: 05/15/2020 TW392538-W_CCN update new labels and certificate of quality_encrypted
Published on: 09/10/2019 190910MXWR-0: Pre-Notification of Replacement of TPE tubing in GE Healthcare Single-Use Assemblies
Published on: 04/03/2020 200403MXWM-1 Gamma irradiation dose range change
Published on: 03/20/2020 200320MXWO-0_GEHC LS Prenotification for Capacity Changes
Published on: 08/22/2019 190822MXWO-1 - Alternate clamp qualified for use in ReadyToProcess™ assemblies
Published on: 08/13/2019 190813RCWC-1 - Revision to Certificate of Quality for ReadyCircuit™ Assembly
Published on: 01/31/2019 180611RMWO-3_GEHC LS_ReadyMate_CCN
Published on: 01/16/2019 180611RMWO-2_GEHC LS_ReadyMate_CCN
Published on: 11/15/2018 180611RMWO-1_GEHC LS_ReadyMate_CCN
Published on: 06/12/2018 180611RMWO-0_GEHC LS_ReadyMate_Prenotification
Published on: 04/17/2018 GEHC LS: Process Change for Westborough, MA Manufactured Single-Use Irradiated Products
Published on: 04/03/2018 Changes to the Certificate of Quality for the ReadyCircuit assembly

ReadyCircuit Tube Set Jumpers

Published on: 04/17/2018 GEHC LS: Process Change for Westborough, MA Manufactured Single-Use Irradiated Products
Published on: 09/10/2019 190910MXWR-0: Pre-Notification of Replacement of TPE tubing in GE Healthcare Single-Use Assemblies
Published on: 05/15/2020 TW392538-W_CCN update new labels and certificate of quality_encrypted
Published on: 04/03/2020 200403MXWM-1 Gamma irradiation dose range change
Published on: 03/20/2020 200320MXWO-0_GEHC LS Prenotification for Capacity Changes
Published on: 03/18/2020 191207RCWR-2 UPDATE Replacement of TPE tubing in GE Healthcare ReadyCircuit™ Standard Jumper Assemblies
Published on: 12/13/2019 191207RCWR-1: Replacement of TPE tubing in GE Healthcare ReadyCircuit™ Standard Jumper Assemblies
Published on: 10/28/2019 190913MXWO-2_ Pinch Clamp UPDATE
Published on: 09/13/2019 Pinch Clamp Change Control Notifcation__190913MXWO-1
Published on: 08/22/2019 190822MXWO-1 - Alternate clamp qualified for use in ReadyToProcess™ assemblies
Published on: 08/13/2019 190813RCWC-1 - Revision to Certificate of Quality for ReadyCircuit™ Assembly
Published on: 01/31/2019 180611RMWO-3_GEHC LS_ReadyMate_CCN
Published on: 01/16/2019 180611RMWO-2_GEHC LS_ReadyMate_CCN
Published on: 11/15/2018 180611RMWO-1_GEHC LS_ReadyMate_CCN
Published on: 06/12/2018 180611RMWO-0_GEHC LS_ReadyMate_Prenotification
Published on: 04/17/2018 GEHC LS: Process Change for Westborough, MA Manufactured Single-Use Irradiated Products
Published on: 04/03/2018 Changes to the Certificate of Quality for the ReadyCircuit assembly

ReadyMate Connectors

Published on: 01/31/2019	180611RMWO-3_GEHC LS_ReadyMate_CCN
Published on: 01/16/2019	180611RMWO-2_GEHC LS_ReadyMate_CCN
Published on: 11/15/2018	180611RMWO-1_GEHC LS_ReadyMate_CCN
Published on: 06/12/2018	180611RMWO-0_GEHC LS_ReadyMate_Prenotification

ReadyToProcess Adsorber

Published on: 03/19/2018	The recommended storage temperature for ReadyToProcess™ Adsorber Phen has been changed from 2-8 °C to room temperature.
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ReadyToProcess Capto Core 400

Published on: 04/05/2019	Change of design of the transportation wheels for ReadyToProcess columns with i.d. 450 mm.
Published on: 03/11/2019	Minor change in packaging of 32 L ReadyToProcess columns

ReadyToProcess Capto Core 700

Published on: 04/01/2019	Change in material and design of ReadyToProcess column parts.
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ReadyToProcess MabSelect Prisma

Published on: 04/01/2019	Change in material and design of ReadyToProcess column parts.
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RTP Column Blue Sepharose Fast Flow

Published on: 04/01/2019	Change in material and design of ReadyToProcess column parts.
Published on: 10/02/2018	Change of material for part in ReadyToProcess columns

RTP Column Butyl-S Sepharose 6 Fast Flow

Published on: 10/02/2018	Change of material for part in ReadyToProcess columns
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RTP Column Butyl Sepharose HP NS

Published on: 04/05/2019	Change of design of the transportation wheels for ReadyToProcess columns with i.d. 450 mm.
Published on: 04/01/2019	Change in material and design of ReadyToProcess column parts.
Published on: 03/11/2019	Minor change in packaging of 32 L ReadyToProcess columns
Published on: 10/02/2018	Change of material for part in ReadyToProcess columns

RTP Column Capto adhere

Published on: 04/05/2019	Change of design of the transportation wheels for ReadyToProcess columns with i.d. 450 mm.
Published on: 04/01/2019	Change in material and design of ReadyToProcess column parts.
Published on: 03/11/2019	Minor change in packaging of 32 L ReadyToProcess columns
Published on: 10/02/2018	Change of material for part in ReadyToProcess columns

RTP Column Capto adhere ImpRes

Published on: 04/05/2019	Change of design of the transportation wheels for ReadyToProcess columns with i.d. 450 mm.
Published on: 04/01/2019	Change in material and design of ReadyToProcess column parts.
Published on: 03/11/2019	Minor change in packaging of 32 L ReadyToProcess columns
Published on: 10/02/2018	Change of material for part in ReadyToProcess columns

RTP Column Capto Butyl

Published on: 04/01/2019	Change in material and design of ReadyToProcess column parts.
Published on: 10/02/2018	Change of material for part in ReadyToProcess columns

RTP Column Capto Butyl ImpRes

Published on: 04/05/2019	Change of design of the transportation wheels for ReadyToProcess columns with i.d. 450 mm.
Published on: 04/01/2019	Change in material and design of ReadyToProcess column parts.
Published on: 03/11/2019	Minor change in packaging of 32 L ReadyToProcess columns
Published on: 10/02/2018	Change of material for part in ReadyToProcess columns

RTP Column Capto Core 700

Published on: 04/01/2019	Change in material and design of ReadyToProcess column parts.
Published on: 10/02/2018	Change of material for part in ReadyToProcess columns

RTP Column Capto DEAE

Published on: 04/01/2019	Change in material and design of ReadyToProcess column parts.
Published on: 10/02/2018	Change of material for part in ReadyToProcess columns

RTP Column Capto L

Published on: 04/05/2019	Change of design of the transportation wheels for ReadyToProcess columns with i.d. 450 mm.
Published on: 04/01/2019	Change in material and design of ReadyToProcess column parts.
Published on: 03/11/2019	Minor change in packaging of 32 L ReadyToProcess columns
Published on: 10/02/2018	Change of material for part in ReadyToProcess columns

RTP Column Capto MMC

Published on: 04/05/2019	Change of design of the transportation wheels for ReadyToProcess columns with i.d. 450 mm.
Published on: 04/01/2019	Change in material and design of ReadyToProcess column parts.
Published on: 03/11/2019	Minor change in packaging of 32 L ReadyToProcess columns
Published on: 10/02/2018	Change of material for part in ReadyToProcess columns

RTP Column Capto MMC ImpRes

Published on: 04/05/2019	Change of design of the transportation wheels for ReadyToProcess columns with i.d. 450 mm.
Published on: 04/01/2019	Change in material and design of ReadyToProcess column parts.
Published on: 03/11/2019	Minor change in packaging of 32 L ReadyToProcess columns
Published on: 10/02/2018	Change of material for part in ReadyToProcess columns

RTP Column Capto phenyl ImpRes

Published on: 04/05/2019	Change of design of the transportation wheels for ReadyToProcess columns with i.d. 450 mm.
Published on: 04/01/2019	Change in material and design of ReadyToProcess column parts.
Published on: 03/11/2019	Minor change in packaging of 32 L ReadyToProcess columns
Published on: 10/02/2018	Change of material for part in ReadyToProcess columns

RTP Column Capto Phenyl (high sub)

Published on: 04/05/2019	Change of design of the transportation wheels for ReadyToProcess columns with i.d. 450 mm.
Published on: 04/01/2019	Change in material and design of ReadyToProcess column parts.
Published on: 03/11/2019	Minor change in packaging of 32 L ReadyToProcess columns
Published on: 10/02/2018	Change of material for part in ReadyToProcess columns

RTP Column Capto Q

Published on: 04/05/2019	Change of design of the transportation wheels for ReadyToProcess columns with i.d. 450 mm.
Published on: 04/01/2019	Change in material and design of ReadyToProcess column parts.
Published on: 03/11/2019	Minor change in packaging of 32 L ReadyToProcess columns
Published on: 10/02/2018	Change of material for part in ReadyToProcess columns

RTP Column Capto Q ImpRes

Published on: 04/05/2019	Change of design of the transportation wheels for ReadyToProcess columns with i.d. 450 mm.
Published on: 04/01/2019	Change in material and design of ReadyToProcess column parts.
Published on: 03/11/2019	Minor change in packaging of 32 L ReadyToProcess columns
Published on: 10/02/2018	Change of material for part in ReadyToProcess columns

RTP Column Capto S

Published on: 04/01/2019	Change in material and design of ReadyToProcess column parts.
Published on: 10/02/2018	Change of material for part in ReadyToProcess columns

RTP Column Capto S ImpAct

Published on: 04/05/2019	Change of design of the transportation wheels for ReadyToProcess columns with i.d. 450 mm.
Published on: 04/01/2019	Change in material and design of ReadyToProcess column parts.
Published on: 03/11/2019	Minor change in packaging of 32 L ReadyToProcess columns

Published on: 10/02/2018 Change of material for part in ReadyToProcess columns

RTP Column Capto SP ImpRes

Published on: 04/05/2019 Change of design of the transportation wheels for ReadyToProcess columns with i.d. 450 mm.
Published on: 04/01/2019 Change in material and design of ReadyToProcess column parts.
Published on: 03/11/2019 Minor change in packaging of 32 L ReadyToProcess columns
Published on: 10/02/2018 Change of material for part in ReadyToProcess columns

RTP Column CM Sepharose Fast Flow

Published on: 04/01/2019 Change in material and design of ReadyToProcess column parts.
Published on: 10/02/2018 Change of material for part in ReadyToProcess columns

RTP Column DEAE Sepharose 6 FF

Published on: 04/01/2019 Change in material and design of ReadyToProcess column parts.
Published on: 10/02/2018 Change of material for part in ReadyToProcess columns

RTP Column Kappa Select

Published on: 04/01/2019 Change in material and design of ReadyToProcess column parts.
Published on: 10/02/2018 Change of material for part in ReadyToProcess columns

RTP Column LambdaFabSelect NS

Published on: 04/01/2019 Change in material and design of ReadyToProcess column parts.
Published on: 10/02/2018 Change of material for part in ReadyToProcess columns

RTP Column MabSelect NS

Published on: 04/05/2019 Change of design of the transportation wheels for ReadyToProcess columns with i.d. 450 mm.
Published on: 04/01/2019 Change in material and design of ReadyToProcess column parts.
Published on: 03/11/2019 Minor change in packaging of 32 L ReadyToProcess columns
Published on: 10/02/2018 Change of material for part in ReadyToProcess columns

RTP Column MabSelect SuRe

Published on: 04/05/2019 Change of design of the transportation wheels for ReadyToProcess columns with i.d. 450 mm.
Published on: 04/01/2019 Change in material and design of ReadyToProcess column parts.
Published on: 03/11/2019 Minor change in packaging of 32 L ReadyToProcess columns
Published on: 10/02/2018 Change of material for part in ReadyToProcess columns

RTP Column MabSelect SuRe LX

Published on: 04/05/2019	Change of design of the transportation wheels for ReadyToProcess columns with i.d. 450 mm.
Published on: 04/01/2019	Change in material and design of ReadyToProcess column parts.
Published on: 03/11/2019	Minor change in packaging of 32 L ReadyToProcess columns
Published on: 10/02/2018	Change of material for part in ReadyToProcess columns

RTP Column MabSelect SuRe pcc

Published on: 04/05/2019	Change of design of the transportation wheels for ReadyToProcess columns with i.d. 450 mm.
Published on: 04/01/2019	Change in material and design of ReadyToProcess column parts.
Published on: 03/11/2019	Minor change in packaging of 32 L ReadyToProcess columns
Published on: 10/02/2018	Change of material for part in ReadyToProcess columns

RTP Column MabSelect Xtra NS

Published on: 04/05/2019	Change of design of the transportation wheels for ReadyToProcess columns with i.d. 450 mm.
Published on: 04/01/2019	Change in material and design of ReadyToProcess column parts.
Published on: 03/11/2019	Minor change in packaging of 32 L ReadyToProcess columns
Published on: 10/02/2018	Change of material for part in ReadyToProcess columns

RTP Column Phenyl Seph 6 FF LS

Published on: 04/01/2019	Change in material and design of ReadyToProcess column parts.
Published on: 10/02/2018	Change of material for part in ReadyToProcess columns

RTP Column Phenyl Sepharose Fast Flow (hs)

Published on: 04/01/2019	Change in material and design of ReadyToProcess column parts.
Published on: 10/02/2018	Change of material for part in ReadyToProcess columns

RTP Column Phenyl Sepharose HP

Published on: 04/05/2019	Change of design of the transportation wheels for ReadyToProcess columns with i.d. 450 mm.
Published on: 04/01/2019	Change in material and design of ReadyToProcess column parts.
Published on: 03/11/2019	Minor change in packaging of 32 L ReadyToProcess columns
Published on: 10/02/2018	Change of material for part in ReadyToProcess columns

RTP Column PlasmidSelect Xtra NS

Published on: 04/01/2019	Change in material and design of ReadyToProcess column parts.
Published on: 10/02/2018	Change of material for part in ReadyToProcess columns

RTP Column Q Sepharose FF

Published on: 04/05/2019	Change of design of the transportation wheels for ReadyToProcess columns with i.d. 450 mm.
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Published on: 04/01/2019	Change in material and design of ReadyToProcess column parts.
Published on: 03/11/2019	Minor change in packaging of 32 L ReadyToProcess columns
Published on: 10/02/2018	Change of material for part in ReadyToProcess columns

RTP Column Q Sepharose HP

Published on: 04/05/2019	Change of design of the transportation wheels for ReadyToProcess columns with i.d. 450 mm.
Published on: 04/01/2019	Change in material and design of ReadyToProcess column parts.
Published on: 03/11/2019	Minor change in packaging of 32 L ReadyToProcess columns
Published on: 10/02/2018	Change of material for part in ReadyToProcess columns

RTP Column Q Sepharose XL

Published on: 04/01/2019	Change in material and design of ReadyToProcess column parts.
Published on: 10/02/2018	Change of material for part in ReadyToProcess columns

RTP Column SP Sepharose 6 FF

Published on: 04/05/2019	Change of design of the transportation wheels for ReadyToProcess columns with i.d. 450 mm.
Published on: 04/01/2019	Change in material and design of ReadyToProcess column parts.
Published on: 03/11/2019	Minor change in packaging of 32 L ReadyToProcess columns
Published on: 10/02/2018	Change of material for part in ReadyToProcess columns

RTP Column SP Sepharose HP

Published on: 04/05/2019	Change of design of the transportation wheels for ReadyToProcess columns with i.d. 450 mm.
Published on: 04/01/2019	Change in material and design of ReadyToProcess column parts.
Published on: 03/11/2019	Minor change in packaging of 32 L ReadyToProcess columns
Published on: 10/02/2018	Change of material for part in ReadyToProcess columns

RTP Column VIIISelect NS

Published on: 04/01/2019	Change in material and design of ReadyToProcess column parts.
Published on: 10/02/2018	Change of material for part in ReadyToProcess columns

RTP Hollow Fiber Cartridges

Published on: 05/15/2020	200424HFWC-3_Implementation Notification_Change to Hollow Fiber BP Spec and CoQ for Cartridges with 0.2 Fiber
Published on: 05/15/2020	TW392538-W_CCN update new labels and certificate of quality_encrypted
Published on: 04/27/2020	200424HFWC-2_Update_Change to Hollow Fiber BP Spec and CoQ for Cartridges with 0.2 (2-E & 2-G) Fiber
Published on: 04/24/2020	200424HFWC-1_Change to Hollow Fiber BP Spec and CoQ for Cartridges with 0.2 (2-E & 2-G) Fiber
Published on: 04/24/2020	200206HFWC-3_Implementation Notification_Change to Hollow Fiber BP Spec and CoQ for 0.45 (4E) fiber
Published on: 04/15/2020	2004015HFWM-1_Ultrafiltration Hollow Fiber Cartridge Air Diffusion Test Procedure and Equipment Updates

Published on: 04/10/2020	200206HFWC-2_Update_Change to Hollow Fiber BP Spec and CoQ for Cartridges with 0.45 (4-E) Fiber
Published on: 04/03/2020	200403MXWM-1 Gamma irradiation dose range change
Published on: 03/20/2020	200320MXWO-0_GEHC LS Prenotification for Capacity Changes
Published on: 02/06/2020	200206HFWC-1_Change to Hollow Fiber Bubble Point Specification & CoQ for Cartridges Containing 0.45 (4-E) Fiber
Published on: 01/14/2020	Correction of Date_191220HFWM-2_Update_Qualification of Hollow Fiber spin line for the manufacture of 500-E fibers
Published on: 01/13/2020	191220HFWM-2_Update_Qualification of Hollow Fiber spin line for the manufacture of 500-E fibers
Published on: 12/20/2019	191220HFWM-1 RTP_Qualification of Hollow Fiber spin line for the manufacture of 500-E fibers
Published on: 12/20/2019	CCN Implementation Update_191112HFWC-1 RTP_Change to Hollow Fiber Bubble Point Specification and Certificate of Quality _20DEC2019
Published on: 11/15/2019	181012RFWM-3_UPDATE to Notification of Addition of Alternate Post-Manufacturing Equipment used for ReadyToProcess™ Hollow Fiber Cartridges
Published on: 11/13/2019	191112HFWC-1 Change to Hollow Fiber Bubble Point Specification and Certificate of Quality for Cartridges Containing 0.65 (6-D) Fiber
Published on: 10/28/2019	190913MXWO-2_Pinch Clamp UPDATE
Published on: 09/13/2019	Pinch Clamp Change Control Notifcation__190913MXWO-1
Published on: 09/10/2019	190910MXWR-0: Pre-Notification of Replacement of TPE tubing in GE Healthcare Single-Use Assemblies
Published on: 08/27/2019	Alternate clamp qualified for use in ReadyToProcess™ assemblies - 190822MXWO-1
Published on: 08/13/2019	190813RCWC-1 - Revision to Certificate of Quality for ReadyCircuit™ Assembly
Published on: 03/27/2019	190327HFWM-1_Implementation of Automation Equipment for ReadyToProcess™ and standard Hollow Fiber Cartridges
Published on: 03/27/2019	190327HFWM-1_Implementation of Automation Equipment for ReadyToProcess™ and standard Hollow Fiber Cartridges
Published on: 01/31/2019	180611RMWO-3_GEHC LS_ReadyMate_CCN
Published on: 01/16/2019	180611RMWO-2_GEHC LS_ReadyMate_CCN
Published on: 12/20/2018	181012RFWM-2_UPDATE of Addition of Alternate Post-Manufacturing Equipment used for ReadyToProcess™ Hollow Fiber Cartridges
Published on: 11/15/2018	180611RMWO-1_GEHC LS_ReadyMate_CCN
Published on: 10/12/2018	181012RFWM-1: Addition of Alternate Post-Manufacturing Equipment used for ReadyToProcess™ Hollow Fiber Cartridges
Published on: 10/12/2018	181012RFWS-1: Change of Manufacturing Site for Component in ReadyToProcess™ Hollow Fiber Cartridges
Published on: 06/12/2018	180611RMWO-0_GEHC LS_ReadyMate_Prenotification
Published on: 04/17/2018	GEHC LS: Process Change for Westborough, MA Manufactured Single-Use Irradiated Products
Published on: 04/11/2018	Manufacturing process change for ReadyToProcess™ hollow fiber cartridges

Change Control Notifications - WAVE

Global Notifications

Published on: 05/15/2020	Notification on Legal Entity changes
Published on: 05/14/2020	Final reminder for Notification on re-designed web page for Change Notifications and Regulatory Support Documentation
Published on: 05/11/2020	Reminderfor Notification on re-designed web page for Cange Notifications and Regulatory Support Documentation.
Published on: 04/27/2020	Update on Notification on re-designed web page for Cange Notifications and Regulatory Support Documentation.
Published on: 04/09/2020	Administrative update of standard for the change control process for designated products

Published on: 04/01/2020	Notification on change of company name
Published on: 03/26/2020	191227MXWS-02 - UPDATE Addition of supplier manufacturing sites for C-Flex® TPE tubing _W
Published on: 03/20/2020	200320MXWO-0_GEHC LS Prenotification for Capacity Changes
Published on: 03/20/2020	Notification on Legal Entity chnages
Published on: 12/27/2019	191227MXWS-01 - Addition of supplier manufacturing sites for C-Flex® TPE tubing_W
Published on: 12/20/2019	Correction to notification regarding Legal entity changes for China
Published on: 11/29/2019	Notification on Legal Entity changes for Russia, China and India
Published on: 10/14/2019	Notification on Company Brand name and Legal Entity changes
Published on: 10/01/2019	Update to Pre-notification on new RS web page published 08 July 2019
Published on: 09/06/2019	Notification on Legal Entity changes - Correction
Published on: 08/30/2019	Notification on Legal Entity changes
Published on: 07/15/2019	Pre-notification on change of company name
Published on: 07/08/2019	Pre-notification new Regulatory Support web page
Published on: 07/06/2018	Update of GE Healthcare Life Sciences' Change Control Standard
Published on: 03/05/2018	Update of GE Healthcare Life Sciences' Change Control Standard

Cellbags

Published on: 05/15/2020	TW392538-W_CCN update new labels and certificate of quality_
Published on: 05/15/2020	200515MXWM-1 - Bag manufacturing process change and new equipment introduction for single-use products manufactured in Westborough, MA, US
Published on: 04/03/2020	200403MXWM-1_Gamma irradiation dose range chang
Published on: 12/19/2019	191219WAWC-1 Changes to all WAVE Certificates of Quality
Published on: 10/28/2019	190913MXWO-2_Pinch Clamp UPDATE
Published on: 09/13/2019	190913MXWO-1_Pinch Clamp Change Control Notifcation
Published on: 09/10/2019	190910MXWR-0: Pre-Notification of Replacement of TPE tubing in GE Healthcare Single-Use Assemblies
Published on: 08/28/2019	180830WAWX-2: Obsolesion of WAVE™ 50L Cellbag (CB0050L10-04)
Published on: 06/20/2018	Changes for Oxywell™ 2 Subassembly: WAVE™ and Xuri™ Cellbags-CCN 180620MXWR-1
Published on: 03/29/2019	190329WAWP-1 - Product revision change for WAVE 20L fortem film cellbag
Published on: 01/31/2019	180611RMWO-3_GEHC LS_ReadyMate_CCN
Published on: 01/16/2019	180611RMWO-2_GEHC LS_ReadyMate_CCN
Published on: 11/15/2018	180611RMWO-1_GEHC LS_ReadyMate_CCN
Published on: 09/10/2018	Revision of the labels and Certificate of Quality (CoQ) for Cellbag™ with Fortem™ film CCN number 180910WAWL-1
Published on: 08/30/2018	Obsolesion of WAVE™ 50L Cellbag (CB0050L10-04) CCN 180830WAWX-1
Published on: 06/20/2018	Changes for Oxywell™ 2 Subassembly: WAVE™ and Xuri™ Cellbags- CCN 180620MXWR-1
Published on: 06/12/2018	180611RMWO-0_GEHC LS_ReadyMate_Prenotification
Published on: 04/17/2018	GEHC LS: Process Change for Westborough, MA Manufactured Single-Use Irradiated Products

Cellbags China

Published on: 03/02/2020

200302MXSM-1 - Process change to include the use of both layers of bag film for China manufactured Cellbag™ Bioreactor bags and ReadyCircuit™ Bag

Published on: 12/20/2019

191220MXSR-1_CCN W_Component changes to Cellbag Bioreactor bags with Fortem film, China, and ReadyCircuit Assemblies, China

Published on: 07/12/2019

190712MXSC-1 GEHC LS Certificate Update for China Manufactured WAVE and ReadyToProcess Bags

Check Valves

Published on: 05/15/2020

TW392538-W_CCN update new labels and certificate of quality_
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Mbags

Published on: 05/15/2020

TW392538-W_CCN update new labels and certificate of quality_
200403MXWM-1_Gamma irradiation dose range chang

Published on: 04/03/2020

191219WAWC-1 Changes to all WAVE Certificates of Quality

Published on: 12/19/2019

190913MXWO-2_Pinch Clamp UPDATE

Published on: 10/28/2019

190913MXWO-1_Pinch Clamp Change Control Notifcation

Published on: 09/13/2019

190910MXWR-0: Pre-Notification of Replacement of TPE tubing in GE Healthcare Single-Use Assemblies

Published on: 09/10/2019

GEHC LS: Process Change for Westborough, MA Manufactured Single-Use Irradiated Products

Published on: 04/17/2018

ReadyToProcess WAVE 25 bioreactor system

Published on: 04/29/2020

Microsoft vulnerability patches for Wave25 and Xuri25 EPC_29-Apr-2020

Published on: 04/27/2020

Microsoft vulnerability patches for Wave25 and Xuri25 EPC_27-Apr-2020

Published on: 03/19/2019

New CO2 sensor for ReadyToProcess CBCU_CCN 19Mar2019

Published on: 10/01/2018

New EPC board for WAVE 25 o Xuri 25_CCN 01Oct2018

Published on: 03/28/2018

New IC for WAVE 25 and Xuri W25_CCN 28-Mar-2018

Sensors

Published on: 05/15/2020

TW392538-W_CCN update new labels and certificate of quality_
200403MXWM-1_Gamma irradiation dose range chang

Published on: 04/03/2020

191219WAWC-1 Changes to all WAVE Certificates of Quality

Published on: 12/19/2019

Sterile Tuber Fuser and Hot Lips Tube Sealer

Published on: 04/26/2019

New front heater for HLTS_CCN 26-Apr-2019

Published on: 12/10/2018

Increased sealing temp in HLTS-II instrument_CCN 10Dec2018

Tubekits

Published on: 05/15/2020

TW392538-W_CCN update new labels and certificate of quality_
200403MXWM-1_Gamma irradiation dose range chang

Published on: 04/03/2020

Published on: 12/19/2019	191219WAWC-1 Changes to all WAVE Certificates of Quality
Published on: 04/17/2018	GEHC LS: Process Change for Westborough, MA Manufactured Single-Use Irradiated Products

Change Control Notifications - Xcellerex

Global Notifications

Published on: 05/15/2020	Notification on Legal Entity changes
Published on: 05/14/2020	Final reminder for Notification on re-designed web page for Change Notifications and Regulatory Support Documentation
Published on: 05/11/2020	Reminder for Notification on re-designed web page for Change Notifications and Regulatory Support Documentation.
Published on: 04/27/2020	Update on Notification on re-designed web page for Change Notifications and Regulatory Support Documentation.
Published on: 04/09/2020	Administrative update of standard for the change control process for designated products
Published on: 04/01/2020	Notification on change of company name
Published on: 03/26/2020	191227MXWS-02 - UPDATE Addition of supplier manufacturing sites for C-Flex® TPE tubing_X
Published on: 03/20/2020	Notification on Legal Entity changes
Published on: 12/27/2019	191227MXWS-01 - Addition of supplier manufacturing sites for C-Flex® TPE tubing_X
Published on: 12/20/2019	Correction to notification regarding Legal entity changes for China
Published on: 11/29/2019	Notification on Legal Entity changes for Russia, China and India
Published on: 10/14/2019	Notification on Company Brand name and Legal Entity changes
Published on: 10/01/2019	Update to Pre-notification on new RS web page published 08 July 2019
Published on: 09/06/2019	Notification on Legal Entity changes - Correction
Published on: 08/30/2019	Notification on Legal Entity changes
Published on: 07/15/2019	Pre-notification on change of company name
Published on: 07/08/2019	Pre-notification new Regulatory Support web page
Published on: 07/06/2018	Update of GE Healthcare Life Sciences' Change Control Standard
Published on: 03/05/2018	Update of GE Healthcare Life Sciences' Change Control Standard

Scales

Published on: 06/01/2018	Regionalized item numbers for scales
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Xcellerex Hardware Accessories

Published on: 01/16/2019	Revised firmware for 530BpN, 630 BpN, and 730 BpN external pumps used with Xcellerex XDR bioreactors and vessels
Published on: 01/11/2019	Replacement of 720BpN external pump used in Xcellerex XDR 50-2000 bioreactors and vessels

Xcellerex XDM-S Quad Stainless Steel Mixing Systems

Published on: 12/18/2019	Change of motor and gearbox used in Xcellerex XDM and Xcellerex XDUO mixing systems
Published on: 09/05/2019	Temperature transmitter used in Xcellerex XDM mixing system
Published on: 04/30/2019	Replacement of resistance temperature (RTD) sensors cables
Published on: 01/17/2019	Change of temperature transmitter in Xcellerex XDM mixing systems
Published on: 12/04/2018	Replacement of Hose Kit assemblies specified with Xcellerex products
Published on: 07/03/2018	Xcellerex RTD sensors updated with a new connector, revised implementation date
Published on: 06/21/2018	Xcellerex RTD sensors updated with a new connector

Xcellerex XDM-T Quad Jacketed Stainless Steel Mixing Systems

Published on: 12/18/2019	Change of motor and gearbox used in Xcellerex XDM and Xcellerex XDUO mixing systems
Published on: 09/05/2019	Temperature transmitter used in Xcellerex XDM mixing systems
Published on: 04/30/2019	Replacement of resistance temperature (RTD) sensors cables
Published on: 01/17/2019	Change of temperature transmitter in Xcellerex XDM mixing systems
Published on: 12/04/2018	Replacement of Hose Kit assemblies specified with Xcellerex products
Published on: 07/03/2018	Xcellerex RTD sensors updated with a new connector, revised implementation date
Published on: 06/21/2018	Xcellerex RTD sensors updated with a new connector

Xcellerex XDM Quad Propylene Mixing Systems

Published on: 12/18/2019	Change of motor and gearbox used in Xcellerex XDM and Xcellerex XDUO mixing systems
Published on: 09/05/2019	Temperature transmitter used in Xcellerex XDM mixing systems
Published on: 04/30/2019	Replacement of resistance temperature (RTD) sensors cables
Published on: 01/17/2019	Change of temperature transmitter in Xcellerex XDM mixing systems
Published on: 12/04/2018	Replacement of Hose Kit assemblies specified with Xcellerex products
Published on: 07/03/2018	Xcellerex RTD sensors updated with a new connector, revised implementation date
Published on: 06/21/2018	Xcellerex RTD sensors updated with a new connector

Xcellerex XDR-10 Bioreactor System, Multi-Vessel

Published on: 02/13/2020	Exhaust filter heater replacement on Xcellerex XDR-10 bioreactor systems
Published on: 05/02/2019	Replacement of transmitter and DCO2 sensor used in Xcellerex™ bioreactors XDR-10, XDR-50 to 2000 bioreactor systems and vessels
Published on: 04/30/2019	Replacement of resistance temperature (RTD) sensors cables
Published on: 01/16/2019	Revised firmware for 530BpN, 630 BpN, and 730 BpN external pumps used with Xcellerex XDR bioreactors and vessels
Published on: 10/01/2018	CIRCUIT BREAKER, 5A, C-CURVE change
Published on: 07/03/2018	Xcellerex RTD sensors updated with a new connector, revised implementation date
Published on: 06/21/2018	Xcellerex RTD sensors updated with a new connector

Xcellerex XDR-10 Bioreactor System, Single Vessel

Published on: 02/13/2020	Exhaust filter heater replacement on Xcellerex XDR-10 bioreactor systems
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Published on: 05/02/2019	Replacement of transmitter and DCO2 sensor used in Xcellerex™ bioreactors XDR-10, XDR-50 to 2000 bioreactor systems and vessels
Published on: 04/30/2019	Replacement of resistance temperature (RTD) sensors cables
Published on: 01/16/2019	Revised firmware for 530BpN, 630 BpN, and 730 BpN external pumps used with Xcellerex XDR bioreactors and vessels
Published on: 10/01/2018	CIRCUIT BREAKER, 5A, C-CURVE change
Published on: 07/03/2018	Xcellerex RTD sensors updated with a new connector, revised implementation date
Published on: 06/21/2018	Xcellerex RTD sensors updated with a new connector

Xcellerex XDR-50 MO Fermentor System

Published on: 10/31/2019	New Model name on MOKON temperature control units
Published on: 06/24/2019	Update of temperature control unit (TCU) kits
Published on: 04/30/2019	Replacement of resistance temperature (RTD) sensors cables
Published on: 01/16/2019	Revised firmware for 530BpN, 630 BpN, and 730 BpN external pumps used with Xcellerex XDR bioreactors and vessels
Published on: 01/11/2019	Replacement of 720BpN external pump used in Xcellerex XDR 50-2000 bioreactors and vessels
Published on: 12/04/2018	Replacement of Hose Kit assemblies specified with Xcellerex products
Published on: 10/01/2018	CIRCUIT BREAKER, 5A, C-CURVE change
Published on: 10/01/2018	Filter heater holder clips change for use with Exhaust Filter Heaters on Xcellerex XDR 50-2000 bioreactor systems and vessels
Published on: 07/03/2018	Xcellerex RTD sensors updated with a new connector, revised implementation date
Published on: 06/21/2018	Xcellerex RTD sensors updated with a new connector

Xcellerex XDR-50 to 2000 Multi-Vessel

Published on: 04/09/2020	MFC mounting plate included in the gas panel on Xcellerex XDR 50-2000
Published on: 01/09/2020	New spare part numbers for Mass Flow Controllers revised
Published on: 10/31/2019	New Model name on MOKON temperature control units
Published on: 06/24/2019	Update of temperature control unit (TCU) kits
Published on: 05/02/2019	Replacement of transmitter and DCO2 sensor used in Xcellerex™ bioreactors XDR-10, XDR-50 to 2000 bioreactor systems and vessels
Published on: 04/30/2019	Replacement of resistance temperature (RTD) sensors cables
Published on: 01/16/2019	Revised firmware for 530BpN, 630 BpN, and 730 BpN external pumps used with Xcellerex XDR bioreactors and vessels
Published on: 01/11/2019	Replacement of 720BpN external pump used in Xcellerex XDR 50-2000 bioreactors and vessels
Published on: 12/04/2018	Replacement of Hose Kit assemblies specified with Xcellerex products
Published on: 10/01/2018	CIRCUIT BREAKER, 5A, C-CURVE change
Published on: 10/01/2018	Filter heater holder clips change for use with Exhaust Filter Heaters on Xcellerex XDR 50-2000 bioreactor systems and vessels
Published on: 07/03/2018	Xcellerex RTD sensors updated with a new connector, revised implementation date
Published on: 06/21/2018	Xcellerex RTD sensors updated with a new connector
Published on: 04/18/2018	New spare part numbers for Mass Flow Controllers

Xcellerex XDR-50 to 2000 Single Vessel

Published on: 04/09/2020	MFC mounting plate included in the gas panel on Xcellerex XDR 50-2000
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Published on: 01/09/2020	New spare part numbers for Mass Flow Controllers revised
Published on: 10/31/2019	New Model name on MOKON temperature control units
Published on: 06/24/2019	Update of temperature control unit (TCU) kits
Published on: 05/02/2019	Replacement of transmitter and DCO2 sensor used in Xcellerex™ bioreactors XDR-10, XDR-50 to 2000 bioreactor systems and vessels
Published on: 04/30/2019	Replacement of resistance temperature (RTD) sensors cables
Published on: 01/16/2019	Revised firmware for 530BpN, 630 BpN, and 730 BpN external pumps used with Xcellerex XDR bioreactors and vessels
Published on: 01/11/2019	Replacement of 720BpN external pump used in Xcellerex XDR 50-2000 bioreactors and vessels
Published on: 12/04/2018	Replacement of Hose Kit assemblies specified with Xcellerex products
Published on: 10/01/2018	CIRCUIT BREAKER, 5A, C-CURVE change
Published on: 10/01/2018	Filter heater holder clips change for use with Exhaust Filter Heaters on Xcellerex XDR 50-2000 bioreactor systems and vessels
Published on: 07/03/2018	Xcellerex RTD sensors updated with a new connector, revised implementation date
Published on: 06/21/2018	Xcellerex RTD sensors updated with a new connector
Published on: 04/18/2018	New spare part numbers for Mass Flow Controllers

Xcellerex XDR-MO 500

Published on: 01/09/2020	New spare part numbers for Mass Flow Controllers revised
Published on: 10/31/2019	New Model name on MOKON temperature control units
Published on: 06/24/2019	Update of temperature control unit (TCU) kits
Published on: 01/16/2019	Revised firmware for 530BpN, 630 BpN, and 730 BpN external pumps used with Xcellerex XDR bioreactors and vessels
Published on: 01/11/2019	Replacement of 720BpN external pump used in Xcellerex XDR 50-2000 bioreactors and vessels
Published on: 12/04/2018	Replacement of Hose Kit assemblies specified with Xcellerex products
Published on: 10/01/2018	CIRCUIT BREAKER, 5A, C-CURVE change
Published on: 10/01/2018	Filter heater holder clips change for use with Exhaust Filter Heaters on Xcellerex XDR 50-2000 bioreactor systems and vessels
Published on: 07/03/2018	Xcellerex RTD sensors updated with a new connector, revised implementation date
Published on: 06/21/2018	Xcellerex RTD sensors updated with a new connector
Published on: 04/18/2018	New spare part numbers for Mass Flow Controllers

Xcellerex XDUO 2500 Mixer

Published on: 12/18/2019	Change of motor and gearbox used in Xcellerex XDM and Xcellerex XDUO mixing systems
Published on: 04/30/2019	Replacement of resistance temperature (RTD) sensors cables
Published on: 12/04/2018	Replacement of Hose Kit assemblies specified with Xcellerex products
Published on: 07/03/2018	Xcellerex RTD sensors updated with a new connector, revised implementation date
Published on: 06/21/2018	Xcellerex RTD sensors updated with a new connector

XDA Accessories

Published on: 12/19/2019	191219XDWC-1 - Xcellerex™ Assure Probe Sheath Accessory documentation and packaging changes
Published on: 08/02/2019	190802XDWC-1 - Editorial changes to the Certificate of Quality (CoQ) and Product Label for the Xcellerex™ Assure Probe Sheath Accessory

Published on: 04/05/2019	190405XDWO-1 - Xcellerex™ XDM Hopper Product Enhancement and Implementation of Regulatory Claims
Published on: 01/31/2019	180611RMWO-3_GEHC LS_ReadyMate_CCN
Published on: 01/16/2019	180611RMWO-2_GEHC LS_ReadyMate_CCN
Published on: 12/04/2018	181204XDWO-1: Xcellerex™ Disposable Assembly (XDA) Product Name Harmonization
Published on: 11/15/2018	180611RMWO-1_GEHC LS_ReadyMate_CCN
Published on: 09/07/2018	Clarification to Notification of change in chain of custody for Xcellerex™ Single Use assemblies and accessories
Published on: 09/06/2018	180906XDWC-1 Transfer of Site Quality Plan for Xcellerex™ Single Use Assemblies
Published on: 07/27/2018	Update to the Change in the Kleenpak™ Connector in Xcellerex™ Disposable Bag Assemblies
Published on: 06/19/2018	UPDATE: Dual sourcing and manufacturing process changes for Xcellerex™ Probe Sheath Accessory - implementation date change
Published on: 06/12/2018	180611RMWO-0_GEHC LS_ReadyMate_Prenotification
Published on: 04/12/2018	Dual sourcing and manufacturing process changes for Xcellerex™ Probe Sheath Accessory
Published on: 02/02/2018	Alignment of Vendor Lot Number and Manufacturer Lot Number for Xcellerex™ Probe Sheath Accessory

XDM Mixing Bags

Published on: 09/10/2019	190910MXWR-0: Pre-Notification of Replacement of TPE tubing in GE Healthcare Single-Use Assemblies
Published on: 04/13/2020	180727XDWR-3 - UPDATE - Product Component Changes to Xcellerex™ Assemblies – additional affected products
Published on: 03/20/2020	200320MXWO-0_GEHC LS Prenotification for Capacity Changes
Published on: 11/08/2019	191108XDWD-1_Editorial changes to Xcellerex™ Disposable Assembly (XDA) Product Documentation
Published on: 07/31/2019	190731XDWF-1 - Change to the Sample Line Length of Standard Xcellerex™ Disposable Mixers (XDM)
Published on: 07/09/2019	190709XDWF-1: Change to the Port Configuration and Sample Line Length of Xcellerex™ Disposable Mixers (XDM) Plus Bag Assemblies
Published on: 04/05/2019	190405XDWO-1 - Xcellerex™ XDM Hopper Product Enhancement and Implementation of Regulatory Claims
Published on: 02/12/2019	180406XDWF-3 - Clarification on Change to the 2500L Xcellerex™ XDM Mixing Bag's Impeller Design and Material of Construction
Published on: 01/31/2019	180611RMWO-3_GEHC LS_ReadyMate_CCN
Published on: 01/16/2019	180611RMWO-2_GEHC LS_ReadyMate_CCN
Published on: 12/04/2018	181204XDWO-1: Xcellerex™ Disposable Assembly (XDA) Product Name Harmonization
Published on: 11/16/2018	181116XDWC-1 Changes to the Certificate of Compliance (CoC) for Xcellerex™ Single Use Bag Assemblies
Published on: 11/15/2018	180611RMWO-1_GEHC LS_ReadyMate_CCN
Published on: 10/18/2018	180727XDWR-2 - Product Component Changes to Xcellerex™ Assemblies –Phase Two Notification and Update on Phase One Implementation
Published on: 09/07/2018	Clarification to Notification of change in chain of custody for Xcellerex™ Single Use assemblies and accessories
Published on: 09/06/2018	180906XDWC-1 Transfer of Site Quality Plan for Xcellerex™ Single Use Assemblies
Published on: 07/27/2018	Update to the Change in the Kleenpak™ Connector in Xcellerex™ Disposable Bag Assemblies
Published on: 07/27/2018	Product component changes to Xcellerex™ Assemblies – Phase One
Published on: 07/17/2018	Update to Change to the 2500L Xcellerex™ XDM Mixing Bag's Impeller Design and Material of Construction
Published on: 04/06/2018	Change to the 2500L Xcellerex™ XDM Mixing Bag's Impeller Design and Material of Construction
Published on: 01/19/2018	GEHC Revision Number Change for Xcellerex Mixing Bag 888-0462-C

XDR Bioreactor Bags

Published on: 09/10/2019	190910MXWR-0: Pre-Notification of Replacement of TPE tubing in GE Healthcare Single-Use Assemblies
Published on: 04/13/2020	180727XDWR-3 - UPDATE - Product Component Changes to Xcellerex™ Assemblies – additional affected products
Published on: 03/25/2020	200325XDWF-01 - Xcellerex Bioreactor (XDR) Impeller Base Geometry Change
Published on: 03/20/2020	200320MXWO-0_GEHC LS Prenotification for Capacity Changes
Published on: 01/03/2020	200103XDWD-1 - Correction of Design Changes for Standard Xcellerex™ Bag assemblies
Published on: 11/08/2019	191108XDWD-1_Editorial changes to Xcellerex™ Disposable Assembly (XDA) Product Documentation
Published on: 01/31/2019	180611RMWO-3_GEHC LS_ReadyMate_CCN
Published on: 01/16/2019	180611RMWO-2_GEHC LS_ReadyMate_CCN
Published on: 12/17/2018	181217XDWF-01 - Replacement of Sterilizing Grade Gas Filters on Xcellerex™ XDR-10 Disposable Bioreactor Bags
Published on: 12/04/2018	181204XDWO-1: Xcellerex™ Disposable Assembly (XDA) Product Name Harmonization
Published on: 11/16/2018	181116XDWC-1 Changes to the Certificate of Compliance (CoC) for Xcellerex™ Single Use Bag Assemblies
Published on: 11/15/2018	180611RMWO-1_GEHC LS_ReadyMate_CCN
Published on: 10/18/2018	180727XDWR-2 - Product Component Changes to Xcellerex™ Assemblies –Phase Two Notification and Update on Phase One Implementation
Published on: 09/07/2018	Clarification to Notification of change in chain of custody for Xcellerex™ Single Use assemblies and accessories
Published on: 09/06/2018	180906XDWC-1 Transfer of Site Quality Plan for Xcellerex™ Single Use Assemblies
Published on: 07/27/2018	Update to the Change in the Kleenpak™ Connector in Xcellerex™ Disposable Bag Assemblies
Published on: 07/27/2018	Product component changes to Xcellerex™ Assemblies – Phase One

XDUO-S Quad Stainless Steel Mixing Systems

Published on: 12/18/2019	Change of motor and gearbox used in Xcellerex XDM and Xcellerex XDUO mixing systems
Published on: 12/04/2019	Replacement of Screw terminal type Safety Relay in Xcellerex XDUO 100-1000 Mixing Systems
Published on: 04/30/2019	Replacement of resistance temperature (RTD) sensors cables
Published on: 12/04/2018	Replacement of Hose Kit assemblies specified with Xcellerex products
Published on: 07/03/2018	Xcellerex RTD sensors updated with a new connector, revised implementation date
Published on: 06/21/2018	Xcellerex RTD sensors updated with a new connector

XDUO-T Quad Jacketed Stainless Steel Mixing Systems

Published on: 12/18/2019	Change of motor and gearbox used in Xcellerex XDM and Xcellerex XDUO mixing systems
Published on: 12/04/2019	Replacement of Screw terminal type Safety Relay in Xcellerex XDUO 100-1000 Mixing Systems
Published on: 04/30/2019	Replacement of resistance temperature (RTD) sensors cables
Published on: 12/04/2018	Replacement of Hose Kit assemblies specified with Xcellerex products
Published on: 07/03/2018	Xcellerex RTD sensors updated with a new connector, revised implementation date
Published on: 06/21/2018	Xcellerex RTD sensors updated with a new connector