

Certificate US23/00000440

The quality management system of

SGS

Pall Medical, a Division of Pall International Sàrl

Avenue de Tivoli 3, 1700 Fribourg, Switzerland

Facility number: F006829

has been assessed and certified as meeting the requirements of

MDSAP (ISO 13485:2016)

Australia: Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 1 - Full Quality Assurance System

Brazil: RDC ANVISA n. 665/2022 - Good Manufacturing Practices; RDC ANVISA n. 551/2021; RDC ANVISA n. 67/2009 - Vigilance

Canada: Medical Device Regulations SOR/98-282, Part 1

USA: 21 CFR Part 803 - Medical Device Reporting; 21 CFR Part 806 - Reports of Corrections and Removals; 21 CFR Part 807 (Subparts A to D) - Establishment Registration and Device Listing, 21 CFR Part 820 - Quality System Regulation

For the following activities

Design and development and manufacture of medical filters, (breathing filters, gas line filters, intravenous filters, extracorporeal filters, blood filters and syringe filters) for general hospital applications; cord blood collection bags for harvesting STEM Cells for cord blood/stem cell collection, processing, transplant and freezing systems and red blood cell harvest filter systems for blood storage.

This certificate is valid from Effective date 2023-10-27 until Expiry date 2026-09-25 and remains valid subject to satisfactory surveillance audits.

Issue 2. Certified since 2023-09-26

Certified activities performed by additional sites are listed on subsequent pages.

L. Henderson

Authorised by

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SGS UK LTD is recognised under the Medical Devices Single Audit Program. The validity of this certificate can be verified at www.SGS.com.



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Pall Medical, a Division of Pall International Sàrl

MDSAP (ISO 13485:2016)

Issue 2
Sites
<p>Pall Medical, a Division of Pall International Sàrl Avenue de Tivoli 3, 1700 Fribourg, Switzerland</p> <p>Administration, Governance, Marketing Authorization, Quality Management, Regulatory Affairs, of all devices under the scope of certification.</p>
<p>Global Life Sciences Solutions Operations UK Ltd 5 Harbournate Business Park, Southampton Road, Portsmouth, PO6 4BQ, United Kingdom</p> <p>Facility number: F006831</p> <p>Design and development of medical filters, (breathing filters, gas line filters, intravenous filters, extracorporeal filters, blood filters and syringe filters) for general hospital applications; cord blood collection bags for harvesting STEM Cells for cord blood/stem cell collection, processing, transplant and freezing systems and red blood cell harvest filter systems for blood storage.</p>
<p>Global Life Sciences Solutions USA LLC 100 Results Way, Marlborough, MA 01752, United States of America</p> <p>Facility number: F006832</p> <p>Regulatory Affairs and support for the devices including medical filters, (breathing filters, gas line filters, intravenous filters, extracorporeal filters, blood filters and syringe filters) for general hospital applications; cord blood collection bags for harvesting STEM Cells for cord blood/stem cell collection, processing, transplant and freezing systems and red blood cell harvest filter systems for blood storage.</p>



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