Certificate US23/00000440

The quality management system of

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 665/2022 - Good Manufacturing Practices; RDC ANVISA n. 551/2021 - Field Actions; RDC ANVISA n. 67/2009 - Vigilance
Canada: Medical Devices Regulations (SOR/98-282) Part 1 - General
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 Management System Regulation

For the following activities
Design and development and manufacture of medical filters, (sterile and non-sterile breathing filters, and gas line filters; sterile intravenous filters, water filters and syringe filters) for general hospital applications; sterile cord blood collection bags for harvesting STEM Cells for cord blood/stem cell collection, processing, transplant and freezing systems for blood storage.

This certificate is valid from Effective date 2026-09-26 until Expiry date 2029-09-25 and remains valid subject to satisfactory surveillance audits.
Issue 6. Certified since 2023-09-26
Certified activities performed by additional sites are listed on subsequent pages.

Authorised by
Virginie Siloret
Head of Certification and Compliance
SGS United Kingdom Ltd
Rossmore Business Park, Ellesmere Port, Cheshire, CH65 3EN, UK
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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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Certificate US23/00000440, continued

Pall Medical, a Division of Pall International Sàrl

MDSAP (ISO 13485:2016)

Issue 6

Sites

Pall Medical, a Division of Pall International Sàrl
Avenue de Tivoli 3, 1700 Fribourg, Switzerland
Facility number: F006829
Administration, Governance, Marketing Authorization, Quality Management, Regulatory Affairs, of all devices under the scope of certification.

Global Life Sciences Solutions Operations UK Ltd.
5 Harbourgate Business Park, Southampton Road, Portsmouth, PO6 4BQ, United Kingdom
Facility number: F006831

Design and development of medical filters, (sterile and non-sterile breathing filters, and gas line filters; sterile intravenous filters, water filters and syringe filters) for general hospital applications; sterile cord blood collection bags for harvesting STEM Cells for cord blood/stem cell collection, processing, transplant and freezing systems for blood storage.

Global Life Sciences Solutions USA LLC
100 Results Way, Marlborough, MA 01752, United States of America
Facility number: F006832

Regulatory Affairs and support for medical filters, (sterile and non-sterile breathing filters, and gas line filters; sterile intravenous filters, water filters and syringe filters) for general hospital applications; sterile cord blood collection bags for harvesting STEM Cells for cord blood/stem cell collection, processing, transplant and freezing systems for blood storage.

Pall Manufacturing UK Ltd dba Pall Newquay
St. Columb Major, Newquay Cornwall, TR9 6TT, United Kingdom
Facility number: F007372

Manufacture of all devices under the scope of certification

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