

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 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, (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 and sterile red blood cell harvest filter systems for blood storage.

This certificate is valid from Effective date 2025-03-20 until Expiry date 2026-09-25 and remains valid subject to satisfactory surveillance audits.

Issue 4. Certified since 2023-09-26

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



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](http://www.SGS.com).



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Certificate US23/00000440, continued

# Pall Medical, a Division of Pall International Sàrl



## MDSAP (ISO 13485:2016)

Issue 4

### Sites

Pall Medical, a Division of Pall International Sàrl  
Avenue de Tivoli 3, 1700 Fribourg, Switzerland

Administration, Governance, Marketing Authorization, Quality Management, Regulatory Affairs, for 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 and sterile red blood cell harvest filter 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 and sterile red blood cell harvest filter systems for blood storage.

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

Manufacture of all devices under the scope of certification.

Campus:  
Hangar NH2, Cornwall Airport, Newquay, TR8 4RQ, United Kingdom



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