

Certificate of Approval

This is to certify that the Management System of:

Pall Medical - A Division of Pall International Sarl

Avenue de Tivoli 3, 1700 Fribourg, Switzerland

MDSAP Facility Identifier : F005291

has been audited by Lloyd's Register Quality Assurance and found to conform to the following audit criteria:

ISO 13485:2016

Australia:

Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1
(Excluding Part 1.6) – Full Quality Assurance Procedure

Brazil:

RDC ANVISA n. 16/2013
RDC ANVISA n. 23/2012
RDC ANVISA n. 67/2009

Canada:

Medical Devices Regulations – Part 1- SOR 98/282

United States:

21 CFR 803
21 CFR 806
21 CFR 807 – Subparts A to D
21 CFR 820
21 CFR 821

Approval number: MDSAP – 00021303

This certificate is valid only in association with the certificate schedule bearing the same number on which the locations applicable to this approval are listed.

The scope of this approval is applicable to:

Design and manufacture of medical filters, including breathing filters, gas line filters, intravenous filters, extracorporeal filters, blood filters and syringe filters for general hospital applications and cord blood/stem cell collection, processing, transplant and freezing systems and cell harvest filter systems.



David Derrick

Area Operations Manager UK & Ireland

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Certificate Schedule

Location	Activities
<p>Facility ID F003689 Avenue de Tivoli 3, 1700 Fribourg, Switzerland</p>	<p>MDSAP 2017 Design and manufacture of medical filters, including breathing filters, gas line filters, intravenous filters, extracorporeal filters, blood filters and syringe filters for general hospital applications and cord blood/stem cell collection, processing, transplant and freezing systems and cell harvest filter systems.</p>
<p>Facility ID F004090 Pall Europe Ltd, 5 Harbourgate Business Park, Southampton Road, Portsmouth, PO6 4BQ, United Kingdom</p>	<p>MDSAP 2017 Design and Development.</p>
<p>Pall Corporation Facility ID F005291 25 Harbor Park Drive, Port Washington, New York, 11050, United States</p>	<p>MDSAP 2017 Device Marketing Authorization and Facility Registration; Device Complaint Monitoring, Mandatory Reporting, Corrections, and Removals.</p>
<p>Pall Filtration Pte Ltd Facility ID F005292 1 Science Park Road, #05-09, East Wing, The Capricorn, Singapore Science Park II, Singapore 117528, Singapore</p>	<p>MDSAP 2017 Device Marketing Authorization and Facility Registration; Medical Device Adverse Events and Advisory Notice Reporting</p>



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