

EC CERTIFICATE – FULL QUALITY ASSURANCE SYSTEM

**In accordance with the requirements of the Medical Devices
Directive 93/42/EEC and the Medical Devices Regulations 2002, UK
Statutory Instrument 2002 No. 618**

This is to certify that the Quality Management System of:

**Pall Medical - A Division of Pall International Sàrl
Avenue de Tivoli 3,
CH-1700 Fribourg
Switzerland**

has been assessed against the requirements of Annex II (excluding Section 4) of the Medical Devices Directive 93/42/EEC, and the Medical Devices Regulations 2002 and conforms to the requirements for the products shown on the attached schedule.

Approval is subject to the maintenance of the quality system in accordance with the requirements of the above Directive and Regulations.

Authorisation is hereby given to use the LRQA Notified Body Registration Number in accordance with the requirements of the specified Directives/Regulations in relation to the products as identified above.

Certificate No: LRQ 4005514/C

Original Approval: 8 January 2010

Current Certificate: 9 July 2019

Certificate Expiry: 7 Jan 2022

LRQA Notified Body Number 0088



Issued by: Lloyd's Register Quality Assurance Limited

**EC CERTIFICATE – FULL QUALITY ASSURANCE SYSTEM
CERTIFICATE LRQ 4005514/C SCHEDULE**

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Class IIa Products

Extracorporeal Filters – AV variants
Extracorporeal Filters – LG6 variants
Extracorporeal Filters – BC2 variants
Extracorporeal Filters – AL6 variants
Extracorporeal Filters – AL3 variants
Extracorporeal Filters – AL20 variants
Breathing Filters – BB50 (Non-sterile) variants
Breathing Filters – BB50 (Sterile) variants
Breathing Filters – BB22-15 (Non-sterile) variants
Breathing Filters – BB22-15 (Sterile) variants
Breathing Filters – BB25 & BB2000 (Non-sterile) variants
Breathing Filters – BB25 & BB2000 (Sterile) variants
Breathing Filters – BB100 (Non-sterile) variants
Breathing Filters – "Ultipor" 100 (Non-sterile) variants
Breathing Filters – "Ultipor" 100 (Sterile) variants
Breathing Filters – PF30 variants
Breathing Filters – MIRUS Filter variants
Breathing Filters – Mouthpiece variants
Gas Line Filters – BB (Non-sterile) variants
Gas Line Filters – BB (Sterile) variants
Gas Line Filters – BRO variants
Gas Line Filters – ORO variants
Gas Line Filters – IGF1 variants
IV Filters – AEF1 variants
IV Filters – ELD variants
IV Filters – NEO96 variants
IV Filters – NLF1 variants
IV Filters – TNA1 variants
IV Filters – TNA2 variants
IV Filters – NLF2 variants
Smoke Filters

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Class IIa Products Continued

Syringe Filters – Supor media variants
Syringe Filters – Versapor media variants
Syringe Filters – Polyester media variants
Vent and Barrier Filters – Versapor media variants (air vent applications)
Vent and Barrier Filters – Versapor media variants (transducer protector applications)

Class IIb Products

Cell harvest filter systems (sterile)- CH-WB variants
Cord Blood/Stem Cell Collection, Processing, Transplant and Freezing Systems (sterile)
Anaesthetic Gas Delivery Absorber / Desorber Devices (non-sterile)– MIRUS Reflector variant

Schedule Issue: 01

Date of Schedule Issue: 9 July 2019

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