



n. **ECM21MDD015 rev. 0**

Data di prima emissione * **08/01/2010**
Date of first issue
Data di emissione **20/05/2021**
Date of issue
Data di ultimo rinnovo
Date of last renewal
Data di revisione
Date of revision
Data di scadenza **26/05/2024**
Expiry date

CERTIFICATO CE EC Certificate

Rilasciato ai sensi della direttiva 93/42/CEE – Allegato II (escl. p.to 4)
Issued according to 93/42/EEC directive – Annex II (excl. clause 4)

Richiedente Applicant

Ragione Sociale
Company Name

Pall Medical, a Division of Pall International Sàrl

Sede Legale
Legal address

Avenue de Tivoli 3, CH-1700 Fribourg

Località
Place

Switzerland

Sito produttivo
Place of production

Same as above

Dispositivo Medico
Medical device

Extracorporeal Filters; Breathing filters; Gas Line Filters; IV Filters; Smoke Filters; Syringe Filters; Vent and Barrier Filters; Cord Blood/Stem Cell Collection, Processing, Transplant and Freezing Systems; Cell Harvest Filter Systems; Anaesthetic Gas Delivery Absorber/Desorber Devices.

Identificato come
Identified as

Vedi allegato al presente certificato
See the annex of this certificate

ECM, Organismo Notificato n° 1282 ha verificato il Sistema Qualità limitato agli aspetti di fabbricazione relativi alla garanzia ed al mantenimento della sterilità per i dispositivi di classe Is e in accordo all'allegato II (escluso punto 4) della direttiva 93/42/CEE) per i dispositivi di classe IIa e IIb e ha rilevato che ne soddisfa i requisiti. Si fa riferimento al rapporto di audit di emissione del presente certificato del 21 gennaio 2021; rif. piano di certificazione: Pall-20.01

ECM, Notified Body n° 1282 has verified the Quality System restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions for class Is devices and in accordance with annex II (excluding clause 4) of the 93/42/EEC directive and found that it meets aforesaid requirements. Reference to the audit report related to issue of the present certificate dated 21st January 2021; ref. certification plan: Pall-20.01

Firma autorizzata
Authorized signature

(Federica Secchi - Technical Director)

*certificato rilasciato per la prima volta da altro Organismo di Certificazione
certificate issued for the first time by another Certification Body

Questo certificato, compreso l'allegato (se presente), può essere riprodotto solo integralmente e senza alcuna variazione

Ente Certificazione Macchine srl

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Pag. 1/3

CERTIFICATO CE
EC CERTIFICATE

MDD13_M00 rev. 00 10.12.2020



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Allegato al Certificato CE Annex to EC Certificate

Rilasciato ai sensi della direttiva 93/42/CEE – Allegato II (escl. p.to 4)
Issued according to 93/42/EEC directive – Allegato II (escl. p.to 4)

Elenco dei Dispositivi Medici inclusi in questo certificato List of Medical Devices included in this certificate

Descrizione Description	Classe di rischio Risk class	Codice NBOG NBOG code	Modello Model	Taglie Sizes
Breathing Filters – BB50 (Non-sterile) variants	Ila	MD0101	BB50TE	N/A
Breathing Filters – BB50 (Sterile) variants	Ila	MD0101 + MDS7006	BB50TES	N/A
Breathing Filters – BB22-15 (Non-sterile) variants	Ila	MD0101	BB22-15, BB22-15F, BB22-15M, BB22-15MF	N/A
Breathing Filters – BB22-15 (Sterile) variants	Ila	MD0101 + MDS7006	BB22-15MFS, BB22-15MS, BB22-15S	N/A
Pall Ultipor 25 Breathing System Filter (Non-sterile)	Ila	MD0101	BB25, BB25D, BB25DFG, BB25DG, BB25F, BB25FG, BB25FU, BB25G, BB25N, BB25NG	N/A
Pall Breathing System Filter (Non-sterile)	Ila	MD0101	BB2000AP	N/A
Pall Ultipor 25 Breathing System Filter (Sterile)	Ila	MD0101 + MDS7006	BB25FS, BB25GS, BB25S	N/A
Pall Ultipor 100 Breathing system Filter (Non-sterile)	Ila	MD0101	BB100E, BB100EF, BB100P, BB100PF	N/A
Pall Ultipor 100 Breathing system Filter (Sterile)	Ila	MD0101 + MDS7006	BB100EFS, BB100ES, BB100PFS, BB100PS	N/A
Breathing Filters – PF30 variants	Ila	MD0101	PF30S, PF30SG, PF30SJE, PF30SJC, PF30-KIT1, PF30-KIT2, PF30-KIT3	N/A
Breathing Filters – MIRUS Filter variants	Ila	MD0101	MF1, MF1D	N/A
Breathing Filters – Mouthpiece variants	Ila	MD0101	MPE1	N/A
Anaesthetic Gas Delivery Absorber/Desorber Devices – MIRUS Reflector variants	Ilb	MD0101	MR1	N/A
PALL Ultipor 50 Breathing System Filter	Ila	MD0101	U50	N/A
Cord Blood/Stem Cell Collection, Processing, Transplant and Freezing Systems – 791-02 variants	Ilb	MD0102 + MDS7006	791-02U	N/A
Cord Blood/Stem Cell Collection, Processing, Transplant and Freezing Systems – 791-03 variants	Ilb	MD0102 + MDS7006	791-03U	N/A
Cord Blood/Stem Cell Collection, Processing, Transplant and Freezing Systems – 791-05 variants	Ilb	MD0102 + MDS7006	791-05U	N/A
Cell Harvest Filter Systems – PALL Celeris System for fPC or TNC enrichment	Ilb	MD0102 + MDS7006	CH-WB110B	N/A

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Pag. 2/3

CERTIFICATO CE
EC CERTIFICATE

MDD13_M00,rev.00 10.12.2020



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Cell Harvest Filter Systems – HemaTrate System for fPC or TNC enrichment	IIb	MD0102 + MDS7006	CH-WB110C	N/A
IV Filters – AEF1 variants	IIa	MD0102 + MDS7006	AEF1E, AEF1NTE	N/A
IV Filters – PALL Nanodyne ELD filter	IIa	MD0102 + MDS7006	ELD96LLCE, ELD96LYLE, ELD96NTE	N/A
IV Filters – PALL Nanodyne NEO FILTER	IIa	MD0102 + MDS7006	NEO96E, NEO96NYE	N/A
IV Filters – PALL Lipipor NEO FILTER	IIa	MD0102 + MDS7006	NLF1E	N/A
IV Filters – TNA1 variants	IIa	MD0102 + MDS7006	TNA1E	N/A
IV Filters – TNA2 variants	IIa	MD0102 + MDS7006	TNA2E	N/A
IV Filters – NLF2 variants	IIa	MD0102 + MDS7006	NLF2E, NLF2NTE	N/A
PALL PharmAssure 25 mm syringe filter with low protein binding Supor membrane	IIa	MD0102 + MDS7006	HP1002, HP1012, HP1050	N/A
GARDIAN 25 mm syringe filters, sterile	IIa	MD0102 + MDS7006	6764192	N/A
PALL PharmAssure 32 mm syringe filter with low protein binding Supor membrane	IIa	MD0102 + MDS7006	HP4640, HP4642, HP4644, HP4648	N/A
Syringe Filters – Versapor media variants	IIa	MD0102 + MDS7006	6094184	N/A
Syringe Filters – Polyester media variants	IIa	MD0102 + MDS7006	6644185, 6074185	N/A
Vent and Barrier Filters – PALL PharmAssure 25 mm Hydrophobic vent filter	IIa	MD0102 + MDS7006	HP2002	N/A
PALL Breathing system filter	IIa	MD0101	BB50TE	N/A
Gas Line Filters – BB (Sterile) variants	IIa	MD0101 + MDS7006	BB25S, BB25GS BB50TES	N/A
PALL ORO gas line filter	IIa	MD0101	ORO1H	N/A
PALL insufflator gas line filter	IIa	MD0101 + MDS7006	IGF1, IGF1C, IGF1CD, IGF1E, IGF1L, IGF1M, IGF1R	N/A
PALL LaparoShield Plus laparoscopic smoke filtration system	Is	MD0106 + MDS7006	LSF1	N/A
PALL LaparoShield Plus laparoscopic smoke filter	Is	MD0106 + MDS7006	LSF2	N/A

Firma autorizzata
Authorized signature

(Federica Secchi - Technical Director)

Questo allegato può essere riprodotto solo integralmente e senza alcuna variazione, assieme al certificato a cui si riferisce
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Ente Certificazione Macchine

European Notified Body No. 1282 - Test Laboratory ISO/IEC 17025 PJLA No. 121697
Accredia Certification Body No. 0118PRD - Entity Authorized by Ministry for Inspections D.Lgs 81/2008

Data: 17 Gennaio 2025

Date: 17 January 2025

A CHI DI COMPETENZA **TO WHOMSOEVER IT MAY CONCERN**

Il presente documento modifica l'elenco dei prodotti riportato nel Certificato CE n. **ECM21MDD015 rev.0** rilasciato il 20 maggio 2021 a **Pall Medical, a Division of Pall International Sàrl**.

*This document amends the products listed in the EC Certificate n. **ECM21MDD015 rev.0** issued on May the 20th, 2021 to **Pall Medical, a Division of Pall International Sàrl**.*

Ente Certificazione Macchine s.r.l (Organismo Notificato n. 1282), conferma che i prodotti coperti dal Certificato CE n. **ECM21MDD015 rev.0** rilasciato il 20 maggio 2021 sono i seguenti:

***Ente Certificazione Macchine s.r.l (Notified Body No. NB 1282)**, confirms that the products covered by the EC Certificate n. **ECM21MDD015 rev.0** issued on May the 20th, 2021 are the following:*

Descrizione <i>Description</i>	Classe di rischio <i>Risk class</i>	Codice NBOG <i>NBOG code</i>	Modello <i>Model</i>	Taglie <i>Sizes</i>
Breathing Filters – BB50 (Non-sterile) variants	Ila	MD0101	BB50TE	N/A
Breathing Filters – BB22-15 (Non-sterile) variants	Ila	MD0101	BB22-15, BB22-15F, BB22-15M, BB22-15MF	N/A
Breathing Filters – BB22-15 (Sterile) variants	Ila	MD0101 + MDS7006	BB22-15MFS, BB22-15MS, BB22-15S	N/A
Pall Ultipor 25 Breathing System Filter (Non-sterile)	Ila	MD0101	BB25, BB25D, BB25DFG, BB25DG, BB25F, BB25FG, BB25FU, BB25G, BB25N, BB25NG	N/A
Pall Breathing System Filter (Non-sterile)	Ila	MD0101	BB2000AP	N/A
Pall Ultipor 25 Breathing System Filter (Sterile)	Ila	MD0101 + MDS7006	BB25FS, BB25GS, BB25S	N/A
Pall Ultipor 100 Breathing system Filter (Non-sterile)	Ila	MD0101	BB100E, BB100EF, BB100P, BB100PF	N/A

ENTE CERTIFICAZIONE MACCHINE SRL

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European Notified Body No. 1282 - Test Laboratory ISO/IEC 17025 PJLA No. 121697

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Pall Ultipor 100 Breathing system Filter (Sterile)	Ila	MD0101 + MDS7006	BB100EFS, BB100ES, BB100PFS, BB100PS	N/A
PALL Ultipor 50 Breathing System Filter	Ila	MD0101	U50	N/A
Cord Blood/Stem Cell Collection, Processing, Transplant and Freezing Systems – 791-02 variants	Ilb	MD0102 + MDS7006	791-02U	N/A
Cord Blood/Stem Cell Collection, Processing, Transplant and Freezing Systems – 791-03 variants	Ilb	MD0102 + MDS7006	791-03U	N/A
Cord Blood/Stem Cell Collection, Processing, Transplant and Freezing Systems – 791-05 variants	Ilb	MD0102 + MDS7006	791-05U	N/A
IV Filters – AEF1 variants	Ila	MD0102 + MDS7006	AEF1E, AEF1NTE	N/A
IV Filters – PALL Nanodyne ELD filter	Ila	MD0102 + MDS7006	ELD96LLCE, ELD96LYLE, ELD96NTE	N/A
IV Filters – PALL Nanodyne NEO FILTER	Ila	MD0102 + MDS7006	NEO96E, NEO96NYE	N/A
IV Filters – PALL Lipipor NEO FILTER	Ila	MD0102 + MDS7006	NLF1E	N/A
IV Filters – TNA1 variants	Ila	MD0102 + MDS7006	TNA1E	N/A
IV Filters – TNA2 variants	Ila	MD0102 + MDS7006	TNA2E	N/A
IV Filters – NLF2 variants	Ila	MD0102 + MDS7006	NLF2E, NLF2NTE	N/A
PALL PharmAssure 25 mm syringe filter with low protein binding Supor membrane	Ila	MD0102 + MDS7006	HP1002, HP1012, HP1050	N/A
GARDIAN 25 mm syringe filters, sterile	Ila	MD0102 + MDS7006	6764192	N/A
PALL PharmAssure 32 mm syringe filter with low protein binding Supor membrane	Ila	MD0102 + MDS7006	HP4640, HP4642, HP4644, HP4648	N/A
Syringe Filters – Versapor media variants	Ila	MD0102 + MDS7006	6094184	N/A
Syringe Filters – Polyester media variants	Ila	MD0102 + MDS7006	6644185, 6074185	N/A
Vent and Barrier Filters – PALL PharmAssure 25 mm Hydrophobic vent filter	Ila	MD0102 + MDS7006	HP2002	N/A
Gas Line Filters – BB (Sterile) variants	Ila	MD0101 + MDS7006	BB25S, BB25GS	N/A
PALL ORO gas line filter	Ila	MD0101	ORO1H	N/A



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PALL insufflator gas line filter	Ila	MD0101 + MDS7006	IGF1, IGF1C, IGF1CD, IGF1E, IGF1L, IGF1M, IGF1R	N/A
PALL LaparoShield Plus laparoscopic smoke filtration system	Is	MD0106 + MDS7006	LSF1	N/A
PALL LaparoShield Plus laparoscopic smoke filter	Is	MD0106 + MDS7006	LSF2	N/A

Il presente documento deve essere sempre presentato unitamente al certificato CE.

This document must be always submitted together with the EC certificate.

Luca Bedonni
Ente Certificazione Macchine s.r.l

