



Ente Certificazione Macchine srl

CERTIFICATO n. PGH-2020-006 rev.0
CERTIFICATE No. PGH-2020-006 rev.0

Ente Certificazione Macchine srl Certifica che l'Organizzazione
Certify that the Organization

Pall Medical – A Division of Pall International Sàrl

Avenue de Tivoli 3, 1700 Fribourg, Switzerland

Per il seguente campo di attività
For the following of activities

Design, development, procurement, testing, manufacturing, placing on the market and selling of:

- Sterile and non-sterile non-active filtration medical devices for the prevention of contamination and cross-contamination during patient treatment in hospital environment
- Sterile non-active medical devices for cord-blood/stem cell collection, processing, transplant and freezing systems
- Sterile non-active medical devices for cell harvest filter systems
- Non-sterile non-active medical devices for anaesthetic gas delivery

Technical area 1.1.A

Ha implementato e mantiene un
Has implemented and maintains a

Sistema di Gestione per la Qualità
Quality Management System

che soddisfa i requisiti delle seguenti norme
which fulfils the requirements of the following standard

EN ISO 13485:2016

Data di prima emissione
Date of first issue **12/01/2021**

Data di emissione
Date of issue **12/01/2021**

Data di revisione
Date of revision /

Data di scadenza
Expiry date **11/01/2024**

Firma autorizzata
Authorized signature

(Federica Secchi - Technical Director)

CERTIFICATO ISO 13485
CERTIFICATE ISO 13485

Rev.06 del 13/11/2020

Cer_02 Certificato ISO 13485

Ente Certificazione Macchine srl

Via Ca' Bella 243 – Loc. Castello di Serravalle – 40053 Valsamoggia (BO)

+39 0516705141 +39 0516705156 ecm@entecerma.it www.entecerma.it



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Allegato al CERTIFICATO n. PGH-2020-006 rev.0
Annex to CERTIFICATE No. PGH-2020-006 rev.0

Elenco dei siti inclusi in questo certificato:
List of sites covered by this certificate

Sito Site	Indirizzo Address
Headquarter	Avenue de Tivoli 3, 1700 Fribourg, Switzerland
Medical R&D and regulatory affairs	Pall Europe Ltd, 5, Harbourgate Business Park, Southampton road, Portsmouth PO6 4BQ, UK

Data di emissione:
Date of issue:

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(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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