



02324

Ente Certificazione Macchine srl

CERTIFICATO n. PGH-2020-006 rev.4
CERTIFICATE No. PGH-2020-006 rev.4

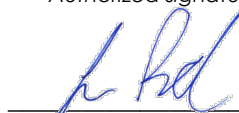
Ente Certificazione Macchine srl

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 activities***Design, development, procurement, testing, management of manufacturing, placing on the market (selling as legal manufacturer) of:**

- non-active filtration medical devices for the prevention of contamination and cross-contamination during patient treatment in hospital environment
- non-active medical devices for cord-blood/stem cell collection, processing, transplant and freezing systems
- non-active medical devices for cell harvest filter systems
- 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 standards***EN ISO 13485:2016**Data di prima emissione
Date of first issue **12th/01/2021**Data di emissione
Date of issue **12th/01/2021**Data di revisione
Date of revision **18th/11/2025**Data di scadenza
Expiry date **11th/01/2027**Firma autorizzata
Authorized signature
(Luca Bedonni - Technical Director)

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

CERTIFICATO ISO 13485
CERTIFICATE ISO 13485

Rev.03 del 05/11/2025

SG13_M02 Certificato ISO 13485



02324

Ente Certificazione Macchine srl

Allegato al CERTIFICATO n. PGH-2020-006 rev.4

Annex to CERTIFICATE No. PGH-2020-006 rev.4

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

Sito Site	Indirizzo Address
Registered place of business and main site	Avenue de Tivoli 3, 1700 Fribourg, Switzerland
Medical R&D and regulatory affairs	Global Life Science Solutions Operations UK Ltd, 5, Harbournate Business Park, Southampton Road, Portsmouth PO6 4BQ, UK

Data di emissione:
Date of issue:

12th/01/2021

Data di revisione:
Date of revision:

18th/11/2025

Firma autorizzata
Authorized signature


(Luca Bedonni - Technical Director)

Questo allegato può essere riprodotto solo integralmente e senza alcuna variazione, assieme al certificato a cui si riferisce
This Annex may only be reproduced in its entirety and without any change, together with the certificate to which it refers

CERTIFICATO ISO 13485

CERTIFICATE ISO 13485

Rev.03 del 05/11/2025

SG13_M02 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