

GMED certifies that the quality management system developed by

MACO PHARMA

Rue Lorthiois

59420 MOUVAUX FRANCE

Facility identifier (REPs-generated) : F004168

for the activities

Conception, production et distribution de dispositifs médicaux pour le prélèvement, le traitement et la conservation du sang, de cellules, d'organes et de tissus. Voir Addendum.

Design, manufacture and distribution of medical devices for the collection, processing and storage of blood, cells, organs and tissues. See addendum.

performed on the location(s) of

Voir addendum / See addendum : Mouvaux - Tourcoing - FRA / Wroclaw - POL / Raoued - TUN

**has been audited and found to conform to the requirements of the international standard
ISO 13485 : 2016 and following regulatory requirements**

Australia	Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure
Brazil	RDC ANVISA n. 665/2022 RDC ANVISA n. 551/2021 RDC ANVISA n. 67/2009
Canada	Medical Devices Regulations - Part 1 - SOR 98/282

Début de validité / Effective date March 28th, 2025 (included)

Valable jusqu'au / Expiry date :March 27th, 2028 (included)

Etabli le / Issued on : July 29th, 2024



GMED is authorised under the Medical Devices Single Audit Program
This certificate is issued according to the rules of GMED Certification
The validity of this certificate can be verified on www.gmed.fr

Renouvelle le certificat 35876-3

DocuSigned by:

Lionel DREUX

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Lionel DREUX
President

Ce certificat couvre les activités et les sites suivants :*This certificate covers the following activities and sites:***Version française :**

Conception, production et distribution de dispositifs médicaux pour le prélèvement, le traitement et la conservation du sang, de cellules, d'organes et de tissus. Calibration des blocs optiques et maintenance des appareils d'illumination. Maintenance de soudeuses et agitateurs.

Version anglaise :

Design, manufacture and distribution of medical devices for the collection, processing and storage of blood, cells, organs and tissues. Calibration of optical blocks and maintenance for illumination equipment. Maintenance for tubes sealers and mixers.

Version française :

Conception, production et distribution de dispositifs médicaux pour :

- Le prélèvement, le traitement et la conservation du sang,
- Le prélèvement, le traitement et la conservation de cellules, d'organes et de tissus.

Calibration des blocs optiques et maintenance des appareils d'illumination. Maintenance de soudeuses et agitateurs.

Version anglaise :

Design, manufacture and distribution of medical devices for:

- Collection, processing and storage of blood,
- Collection, processing and storage of cells, organs and tissues.

Calibration of optical blocks and maintenance for illumination equipment. Maintenance for tubes sealers and mixers

MACO PHARMA Rue Lorthiois – 59420 Mouvaux – France

REPS identification number : F004168

Siège social - Responsable de la mise sur le marché - Conception - Distribution

Headquarters - Legal manufacturer - Design– Distribution

Maco Productions - 200 Chaussée Fernand Forest – 59200 Tourcoing – France

REPS identification number : F004168

Conception - Fabrication - Distribution - Calibration – maintenance

Design - Manufacture - Distribution - Calibration - Maintenance

Version française :

Production et distribution de dispositifs médicaux pour :

- Le prélèvement, le traitement et la conservation du sang,
- Le prélèvement, le traitement et la conservation de cellules, d'organes et de tissus.

Version anglaise :

DocuSigned by:

Lionel DREUX

A1D80E08C60D47A...



Lionel DREUX
President

Manufacture and distribution of medical devices for:

- Collection, processing and storage of blood,
- Collection, processing and storage of cells, organs and tissues.

Maco Productions Polonia – SPÓŁKA Z ORGANICZONĄ ODPOWIEDZIALNOŚCIĄ – 54405**Wroclaw – Pologne****REPS identification number : F004178**

Fabrication – Distribution / Manufacture – Distribution

Version française :

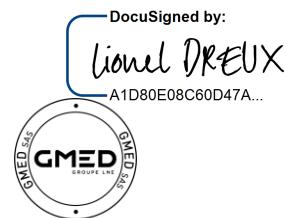
Production et distribution de dispositifs médicaux pour le prélèvement, le traitement et la conservation du sang.

Version anglaise:

Manufacture and distribution of medical devices for collection, processing and storage of blood,

MACO MD : Lot 99 - Zone industrielle Chotrana 2- 2056- Raoued – Ariana – Tunisie**REPS identification number : F004176**

Fabrication – Distribution / Manufacture – Distribution

4 sites / 4 sites

Lionel DREUX
President