

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. Maintenance de dispositifs médicaux et accessoires. Voir Addendum.

Design, manufacture and distribution of medical devices for the collection, processing and storage of blood, cells, organs and tissues. Servicing of medical devices and accessories. 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. 16/2013 RDC ANVISA n. 23/2012 RDC ANVISA n. 67/2009
Canada	Medical Devices Regulations - Part 1 - SOR 98/282

Début de validité / Effective date March 28th, 2022 (included)

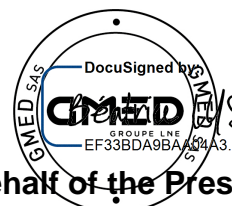
Valable jusqu'au / Expiry date : March 27th, 2023 (included)

Etabli le / Issued on : February 22nd, 2022



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 35876-0



On behalf of the President
Béatrice LYS
Technical Director

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

French version :

- ↻ 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.
- ↻ Maintenance de dispositifs médicaux et accessoires.

English version:

- ↻ *Design, manufacture and distribution of medical devices for:*
 - *Collection, processing and storage of blood,*
 - *Collection, processing and storage of cells, organs and tissues.*
- ↻ *Servicing of medical devices and accessories.*

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 / *Design - Manufacture - Distribution*

French version :

- ↻ 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.

English version:

- ↻ *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 Wrocław – Pologne

REPS identification number : F004178

Fabrication – Distribution / *Manufacture – Distribution*

For signed by:

EF33BDA9BAA04A3...

On behalf of the President
Béatrice LYS
Technical Director

French version :

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

English version:

↻ *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



On behalf of the President
Béatrice LYS
Technical Director

GMED certifies that the quality management system developed by

MACO PHARMA

Rue Lorthiois

59420 MOUVAUX FRANCE

Facility identifier (REPs-generated) : F004168

for the activities

**Production et distribution de dispositifs médicaux
pour le prélèvement de fluides biologiques.**

*Manufacture and distribution of medical devices
for the collection of biological fluids.*

performed on the location(s) of

Voir addendum / See addendum : Mouvaux - Tourcoing - FRA / Wroclaw - 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 4
Production Quality assurance Procedure

Début de validité / Effective date March 28th, 2022 (included)

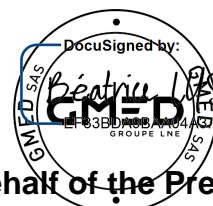
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Renouvelle le certificat 35918-0



**On behalf of the President
Béatrice LYS
Technical Director**

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

French version :

∞ Production et distribution de dispositifs médicaux pour le prélèvement de fluides biologiques.

English version:

∞ *Manufacture and distribution of medical devices for collection of biological fluids.*

Maco Pharma - Rue Lorthois - 59420 Mouvaux – France

REPS identification number: F004168

Siège social – Responsable de la mise sur le marché / *Headquarters – Legal manufacturer*

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

REPS identification number: F004168

Fabrication – Distribution / *Manufacture – Distribution*

Maco Productions Polonia – SPÓŁKA Z ORGANICZONĄ ODPOWIEDZIALNOŚCIĄ – 54405

Wroclaw – Pologne

REPS identification number : F004178

Fabrication – Distribution / *Manufacture – Distribution*

3 sites / 3 sites



Signed by:

Beatrice LYS

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On behalf of the President
Béatrice LYS
Technical Director