CERTIFICATE OF REGISTRATION

N° 38314–4

GMED certifies that the quality management system developed by

HEMODIA SAS
85 rue du Chêne Vert
31670 LABEGE FRANCE

Facility identifier (REPs-generated) : F005298

for the activities

Conception, fabrication et distribution de pompes d'arthroscopie, d'accessoires de pompes d'arthroscopie et de tubulures d'arthroscopie.
Service après-ventes de pompes d'arthroscopie.

Design, manufacturing and distribution of arthroscopy pumps, arthroscopy pumps accessories and arthroscopy tubings.
Servicing of arthroscopy pumps.

performed on the location(s) of

HEMODIA LABEGE SIEGE - 85 rue du Chêne Vert 31670 LABEGE FRA
HEMODIA LABEGE SIEGE - 104 rue du Chêne Vert 31670 LABEGE FRA
HEMODIA LABEGE SIEGE - 28-30 boulevard de Thibaud 31100 TOULOUSE FRA

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
Canada	Medical Devices Regulations - Part 1 - SOR 98/282
Japan	MHLW MO 169 PMD Act
United States	21 CFR 820 21 CFR 803 21 CFR 806 21 CFR 807 - -Subparts A to D

DocuSigned by:
Beatrice Lys
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Début de validité / *Effective date* **May 5th, 2024 (included)**
Valable jusqu'au / *Expiry date :* **May 4th, 2027 (included)**
Etabli le / *Issued on :* **June 26th, 2024**

GMED SAS GMED GROUPE LNE GMED SAS

On behalf of the President
Béatrice LYS
Technical Director

MDSAP MEDICAL DEVICE SINGLE AUDIT PROGRAM

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

Annule et remplace le certificat 38314-3

GMED_MDSAP2016-F-V0-07-