

CERTIFICATE OF REGISTRATION N° 38314-2

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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

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
United States	21 CFR 820 21 CFR 803 21 CFR 806 21 CFR 807Subparts A to D

Début de validité / Effective date August 8th, 2022 (included) Valable jusqu'au / Expiry date : May 4th, 2024 (included)

Etabli le / Issued on : August 8th, 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 Modifie le certificat 38314-1



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Siège social : 1, rue Gaston Boissier - 75015 Paris • Tél. : 01 40 43 37 00 • gmed.fr