CERTIFICATE OF REGISTRATION

N° 36453–1

GMED certifies that the quality management system developed by

MERCODIA AB
Sylveniusgatan 8A
754 50 UPPSALA SWEDEN

Facility identifier (REPs-generated) : F004432

for the activities

Conception et développement, fabrication de kits de diagnostic in vitro pour la détection de métabolites dans différents domaines tels que : les maladies cardio-vasculaires, l'obésité et le diabète.

The design, development and manufacturing of immunoanalysis in vitro diagnostic reagents, used for detection of analytes in areas such as: cardiovascular disease, obesity and diabetes.

performed on the location(s) of

Mercodia AB - Sylveniusgatan 8A - 754 50 Uppsala - SWE

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

Canada	Medical Devices Regulations - Part 1 - SOR 98/282
United States	21 CFR 820 21 CFR 803 21 CFR 806 21 CFR 807 - -Subparts A to D 21 CFR 821 (where applicable)

Début de validité */ Effective date* **February 1st, 2023 (included)**
Valable jusqu'au */ Expiry date :***January 31st, 2026 (included)**
Etabli le */ Issued on :* **January 23rd, 2023**

DocuSigned by:
MARJORIE PERRIMON
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On behalf of the President
Marjorie PERRIMON
Certification Director

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 36453-0

GMED_MDSAP2016-F-V0-07-