

GMED certifies that the quality management system developed by

UNOMEDICAL A/S
Aaholmvej 1-3, Osted
4320 LEJRE DENMARK

Facility identifier (REPs-generated) : F000674

for the activities

Conception, fabrication de sets de perfusion (cannule rigide ou souple, pour insertion en biais ou droite) et sets pour applications thérapeutiques sous cutanées.

Design, manufacturing of infusion sets (rigid and soft cannula, angled and straight insertion), and sets for subcutaneous therapy applications.

performed on the location(s) of

Voir addendum / see addendum: 3 sites MX1 MX2 DNK

**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
Japan	MHLW MO 169 PMD Act
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 November 20th, 2023 (included)

Valable jusqu'au / Expiry date : August 13th, 2026 (included)

Etabli le / Issued on : November 20th, 2023



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 35117-4



On behalf of the President
Béatrice LYS
Technical Director

Résumé des activités couvertes par le certificat / Summary of activities covered by the certificate:

- French version: Conception, fabrication de sets de perfusion (canule rigide ou souple, pour insertion en biais ou droite) et sets pour applications thérapeutiques sous cutanées.
- English version: Design, manufacturing of infusion sets (rigid and soft cannula, angled and straight insertion), and sets for subcutaneous therapy applications.

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

**Unomedical a/s
Aaholmvej 1-3, Osted - 4320 Lejre - Denmark**

D.U.N.S. identification number : 30-603-2491

- French version: Conception, fabrication de sets de perfusion (canule rigide ou souple, pour insertion en biais ou droite) et sets pour applications thérapeutiques sous cutanées.
- English version: Design, manufacturing of infusion sets (rigid and soft cannula, angled and straight insertion), and sets for subcutaneous therapy applications.

**Unomedical Devices S.A De C.V.
Avenida Fomento Industrial, Lote 9, M3 - Parque Industrial del Norte
Reynosa, Tamaulipas
Mexico C.P. 88736**

**Unomedical Devices S.A. De C.V.
Avenida Industrial Falcon, Seccion 4, Lote 7 – Parque Industrial del Norte
Reynosa, Tamaulipas
Mexico C.P. 88736**

D.U.N.S. identification number : 58-820-2874

- French version: Fabrication de sets de perfusion (cannule rigide ou souple, pour insertion en biais ou droite) et sets pour applications thérapeutiques sous cutanées.
- English version: Manufacturing of infusion sets (rigid and soft cannula, angled and straight insertion), and sets for subcutaneous therapy applications.



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