



EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
(Class IIa and Class IIb Devices)

No. G10 054875 0004 Rev. 04

Manufacturer: **Ypsomed AG**
Brunnmattstrasse 6
3401 Burgdorf
SWITZERLAND

SRN Manufacturer - CH-MF-000016749

Authorized Representative: Ypsomed Distribution GmbH
Warmbacher Strasse 80, 79618 Rheinfelden, GERMANY

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s).

The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.

The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.

The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples.

All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with.

For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G10_054875_0004_Rev.04

Report No.: 713266686_CN

Preceding Certificate No.: G10 054875 0004 Rev. 03

Valid from: 2024-03-12

Valid until: 2026-07-01

Date of Initial Issuance: 2021-07-02

Issue date: 2024-03-12
Christoph Dicks
Head of Certification/Notified Body



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Classification: Class IIb
Device Group: A020203 - CARTRIDGE SYRINGES
Intended Purpose: Pen Injectors are non-sterile, reusable pen injector intended for the subcutaneous administration of insulin from compatible Cartridges with a specified dose accuracy.

Classification: Class IIb
Device Group: A03040101 - KITS FOR CONTINUOUS SUBCUTANEOUS INSULIN INFUSION
Intended Purpose: Infusion Sets are used for the continuous subcutaneous delivery of insulin from the external insulin Infusion pump YpsoPump.

Classification: Class IIa
Device Group: A01010102 - HYPODERMIC PEN NEEDLES
Intended Purpose: -

Classification: Class IIa
Device Group: A080201 - INFUSION PUMP BAGS AND CONTAINERS, SINGLE-USE
Intended Purpose: -

The validity of this certificate depends on conditions and/or is limited to the following:

Revision History:

Rev.	Dated	Report	Description
00	2021-07-02	713195173	-
01	2022-09-30	713219927	-
02	2023-07-14	713262835	Amended: Other
03	2023-07-19	713219353	Supplemented: Device(s)/group of device(s) added
04	2024-03-12	71326686_CN	Supplemented: Device(s)/group of device(s) added