

EU MDD Declaration of Conformity

Manufacturer: Ypsomed AG, Brunnmattstrasse 6, 3401 Burgdorf, Switzerland

Product: YpsoPump® Orbit®soft Infusion Set
YpsoPump® Orbit®micro Infusion Set
Orbit®soft Universal Infusion Set Cannula
Orbit®micro Universal Infusion Set Cannula

Types: Soft cannula: 6 mm, 9 mm
Steel cannula: 31G x 5.5 mm, 31G x 8.5 mm
Tubing length: 45 cm, 60 cm, 80 cm, 110 cm

Description: Sterile, single use Infusion Sets intended for the subcutaneous delivery of insulin, from the external YpsoPump® Insulin Infusion Pump

Classification: IIb

Conformity assessment route: 93/42/EEC, Annex II.3 (full quality assurance system)

We herewith declare exclusively under sole responsibility that the above mentioned products meet the provisions of the council directive 93/42/EEC for medical devices. All supporting documentation is retained under the premises of the manufacturer.

Standards applied:

EN ISO 11135:2014 Sterilization of health care products – Ethylene oxide – Requirements for development, validation and routine control of a sterilization process for medical devices

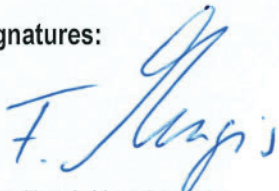
Notified Body: TÜV SÜD Product Service GmbH, Ridlerstrasse 65, 80339 München, Germany; Identification Number 0123

EC Certificate: G1 054875 0003

Start of CE-marking: December 02, 2019

Place, Date of Issue: Burgdorf, December 02, 2019

Signatures:



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Vice President Quality Management & Regulatory Affairs