YPSOMED
SELFCARE SOLUTIONS

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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