

SQS as a conformity assessment body identification number 1250 herewith certifies the company

Ypsomed AG
Brunnmattstrasse 6
3401 Burgdorf
Switzerland

the use of a quality assurance system in its design, development, manufacturing and distribution which fulfills the requirements set out in:

ANNEX II

Directive 93/42/EEC (without section 4)

This approval is based on the report dated April 01, 2019.

The scope of validity covers the products/the product

Injection + Infusion Systems

The following CE label can be applied to these products/the product mentioned in the Appendix of this certificate

CE 1250

A condition for the validity of this certificate is a regular examination in accordance with Annex II.5 of the Directive 93/42/EEC.

Validity 01.05.2019 – 30.04.2024
 Issue 01.05.2019

Reg. no. 22486
 Approved Medical Responsible
 15.04.2019



F. Müller, CEO SQS



D. Taddeo, Medical Responsible



sqs.ch

Swiss Association for Quality and
 Management Systems SQS
 Bernstrasse 103, 3052 Zollikofen, Switzerland



ANNEX II

Directive 93/42/EEC (without section 4)

This Appendix is valid only in connection with the following certificate:

Registration Number 22486

Validity from May 01, 2019 up to and including April 30, 2024

This approval includes the following Medical Device/s:

Class IIb

Infusion Pumps

YpsoPump

Infusion Sets

YpsoPump Orbit soft Infusion Set
YpsoPump Orbit micro Infusion Set
Orbit soft Infusion Set
Orbit soft Infusion Set Cannula
Orbit soft universal Infusion Set Cannula
Orbit micro Infusion Set
Orbit micro Infusion Set Cannula
Orbit micro universal Infusion Set Cannula
Soft-Release-O Infusion Set

Injection Pens

ServoPen

Class IIa

Infusion Pump Accessories

YpsoPump Reservoir

Pen Needles

Penfine Classic
Pen Needle
Clickfine
Optifine
Clickfine AutoProtect

Injection Pens

Servopen Fix
Terrosa Pen
Movymia Pen

Appendix issue date: May 01, 2019

