

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 result of the report dated December 29, 2017.

The scope of validity covers the products

### Injection + Infusion Systems

The following CE label can be applied to the products 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.

Swiss Association for Quality and Management Systems SQS  
Bernstrasse 103, CH-3052 Zollikofen  
Issue date: May 1, 2016  
Date of change: December 29, 2017

This SQS Certificate is valid up to and including April 30, 2019  
Registration number 22486  
Approved Medical Responsible:  
December 29, 2017



Trusted Cert

  
R. Glauser, CEO SQS

  
K. Schulze, Medical Responsible



## 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 1, 2016 up to and including April 30, 2019

**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**

Ypsopen U100

ServoPen

### Class IIa

#### **Infusion Pump Accessories**

YpsoPump Reservoir

#### **Pen Needles**

Penfine universal click

Penfine Classic

Pen Needle

Clickfine

Optifine

Clickfine AutoProtect

#### **Injection Pens**

ServoPen Fix

Terrosa Pen

Movymia Pen

Appendix issue date: December 29, 2017



Trusted Cert



Swiss Made