

Ypsomed AG Brunnmattstrasse 6 Postfach 3401 Burgdorf / Switzerland Tel. +41 34 424 41 11 Fax +41 34 424 41 22 www.ypsomed.com info@ypsomed.com

To whom it may concern

## **Declaration of Conformity**

We, **Ypsomed AG, Brunnmattstrasse 6, 3401 Burgdorf, Switzerland**, declare on our own responsibility that the medical devices manufactured by **Ypsomed AG**:

Name:

Clickfine

Types:

Needle 0.23 mm x 4 mm (32G), 0.25 mm x 5 mm (31G), 0.25 mm x 6 mm (31G), 0.25 mm

x 8 mm (31G), 0.33 mm x 10 mm (29G), 0.33 mm x 12 mm (29G)

Description:

Pen needle for various pen-injector systems, to click on

Class:

lla

meet all applicable requirements of the **European Council Directive 93/42/EEC** concerning medical devices and comply with:

ISO 11608-2:2012

Needle-based injection systems for medical use - Requirements and test methods -

Part 2: Needles

ISO 11137-1:2006

Sterilization of health care products - Radiation - Part 1: Requirements for

development, validation and routine control of a sterilization process for medical

devices

Conformity assessment was performed according to annex II.3 (full quality assurance system) of the European Council Directive 93/42/EEC.

The quality system is certified by the **Notified Body** SQS, Swiss Association for Quality and Management Systems, Zollikofen, Switzerland.

**C € 1250** 

This declaration of conformity is valid for all lots manufactured as of July 07, 2017.

Burgdorf, December, 20, 2017

Simon Michel

Chief Executive Officer

Frank Mengis

Vice President Quality Management & Regulatory Affairs