YPSOMED
SELFCARE SOLUTIONS

EU-MDD Declaration of Conformity

Manufacturer:	Ypsomed AG, Brunnmattstrasse 6, 3401 Burgdorf, Switzerland
Authorised Representative:	Ypsomed Distribution GmbH, Warmbacher Strasse 80, 79618 Rheinfelden, Germany
Product:	**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
Classification:	IIa
Conformity assessment route:	Directive 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:

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

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 01, 2019
Place, Date of Issue:	Burgdorf, May 06, 2020

Signatures:

ppa. Frank Uwe Mengis
Senior Vice President Operations / COO

ppa. Dr. Susana de Azevedo Wäsch
Vice President Quality Management & Regulatory Affairs