

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: Ila

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

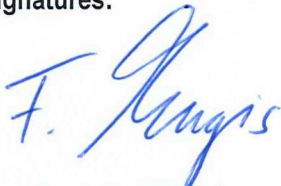
Notified Body: TÜV SÜD Product Service GmbH, Ridlerstrasse 65, 80339 München, Germany;
Identification Number 0123

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 Wäscher
Vice President Quality Management & Regulatory Affairs