

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

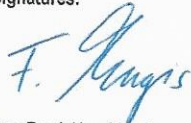
Notified Body: TÜV SÜD Product Service GmbH, Ridlerstrasse 65, 80339 München, Germany;
Identification Number 0123

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



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08



Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 054875 0003 Rev. 00

Manufacturer: **Ypsomed AG**
Brunnmattstrasse 6
3401 Burgdorf
SWITZERLAND

Product Category(ies): Injection and Infusion Systems

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 713152785

Valid from: 2019-12-01
Valid until: 2024-04-30

Date, 2019-11-27

Christoph Dicks
Head of Certification/Notified Body

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Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 054875 0003 Rev. 00

Facility(ies):

Ypsomed AG
Brunnmattstrasse 6, 3401 Burgdorf, SWITZERLAND

Ypsomed AG
Buchmattstrasse 100, 3401 Burgdorf, SWITZERLAND

Ypsomed AG
Lochbachstrasse 26, 3401 Burgdorf, SWITZERLAND

Ypsomed AG
Weissensteinstrasse 26, 4503 Solothurn, SWITZERLAND

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