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

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

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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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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