

EC DECLARATION OF CONFORMITY

MEDICAL DEVICES

Product categories :

Solution for disinfection of dental and surgical instruments and devices, endoscopes, and for use in ultrasonic bathes.

| Brand name : | Type of product : |
|--|--------------------------|
| Helvemed Disinfection Instrument Forte+ | Solution |

Conformity Assessment Procedure

according to ANNEX II.3 of the COUNCIL
DIRECTIVE 93/42/EEC

Classification

according to ANNEX IX of the COUNCIL
DIRECTIVE 93/42/EEC
Class IIb / Rule 15

Applied standards :

EN/ISO 13485:2003/AC 2007, certificate CH07/070
EN/ISO 9001:2008, certificate CH07/069
EC Certificate nr. CH12/1182 valid until 09.06.2021

Notified Body

SGS United Kingdom Ltd.
Systems and Services Certification
202b Worle Parkway
Weston super Mare
BS22 6Wa UK

Identification Nr.

0120

We herewith declare, under our sole responsibility, that the above mentioned products meet all the provisions of the COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices as amended by Directive 2007/47/EC, which apply to them, as stated in ANNEX II.3.

Geneva, June, 20th 2017

HELVEMED SA



Grégoire Weill
CEO