B BRAUN
SHARING EXPERTISE

B. Braun Medical AG
Seesatz 17
6204 Sempach
Switzerland

DECLARATION OF CONFORMITY

FOR MEDICAL DEVICES

Product category: Solutions and powders for disinfection of dental and surgical instruments and devices, endoscopes, anesthetic equipment, hemodialysis monitors and for use in ultrasonic bathes. Wipes for cleansing and disinfection of medical devices as ultrasonic probe heads.

Brand Name	Dosage form	Date of CE marking / Batch number	Remarks
Helimatic® Disinfectant	Solution	11.05.2000	
Helipur®	Solution	29.04.1996	
Helipur® H plus N	Solution	01.02.1998	
Helix® ultra	Powder	01.03.2008 / Batch 0803BH0002	
Meliseptol® Wipes ultra	Wipes	19.02.2016 / Batch 15465M24	
Stabimed®	Solution	01.02.1998	
Stabimed® fresh	Solution	19.09.2013 / Batch 13384M20	
Stabimed® ultra	Powder	18.11.2015 / Batch 1511BH0009	
Tiutol® dent	Solution	29.04.1996	

Conformity Assessment Procedure according to ANNEX II.3 without 4 of the COUNCIL DIRECTIVE 93/42/EEC

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

Applied Standards EN/ISO 13485:2012/AC 2012, Certificate No. Q1N 16 05 61585 016, valid until 31.07.2019.

EC Certificate No. G1 16 05 61585 017; valid until 17.05.2019

Notified Body TÜV SÜD Product Service GmbH, Zertifizierstelle, Ridlerstrasse 65, 80339 München, Germany

Identification no. 0123

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.

Sempach, 08.08.2016

B. Braun Medical AG

Sandro Di Labio
Head of Quality Management

Dr. Michael Gluschke
Head of Regulatory Affairs