

B. Braun Medical AG
Seesatz 17
6204 Sempach
Switzerland

DECLARATION OF CONFORMITY

Product category: Solutions and powders for disinfection of dental and surgical instruments and devices, endoscopes, anesthetic equipment, hemodialysis monitors and for use in ultrasonic baths. Wipes for cleaning 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	
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	

Article numbers: see attachment

Conformity Assessment Procedure

according to ANNEX II excluding (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 13485:2016, Certificate No. Q5 18 05 61585 027,
valid until 31.07.2019.

EC Certificate

No. G1 061585 0032; valid until 17.05.2024

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, 27.05.2019

B. Braun Medical AG


Peter Egli
Head of Quality Unit CoE Infection Control


Dr. Michael Gluschke
Director Global Regulatory Affairs OPM

DECLARATION OF CONFORMITY
Attachment for Medical Devices Class IIb

Art. No.	Product Name	Remarks
18562	Helimatic® Disinfectant, 5 l	
18982	Helimatic® Disinfectant, 5 l	
18894	Helipur®, 1000 ml	
18895	Helipur®, 5 l	
18940	Helipur® H plus N, 1000 ml	
18941	Helipur® H plus N, 5 l	
3891950	Helipur® H plus N, 1000 ml	
3892212	Helipur® H plus N, 5 l	
19810	Meliseptol® Wipes ultra, 100 Tissues	
180014	Meliseptol® Wipes ultra, 100 Tissues	
18778	Stabimed®, 1000 ml	M3/V3 (TW 148405) – 31.12.2019
18779	Stabimed®, 5 l	M3/V3 (TW 118399) – 31.12.2019
18850	Stabimed®, 5 l	M3/V3 (TW 118399) – 30..09.2019
18986	Stabimed®, 1000 ml	M3/V3 (TW 147359) – 31.05.2020
19094	Stabimed®, 1000 ml	M3/V3 (TW 148405) – 31.12.2019
19095	Stabimed®, 5 l	M3/V3 (TW 118399) – 31.12.2019
19689	Stabimed® fresh, 1000 ml	
19690	Stabimed® fresh, 5 l	
19828	Stabimed® fresh, 5 l	
19829	Stabimed® fresh, 1000 ml	
19860	Stabimed® fresh, 1000 ml	
19861	Stabimed® fresh, 5 l	
19767	Stabimed® ultra, 800 g	
19812	Stabimed® ultra, 6x800 g	
19813	Stabimed® ultra, 4 kg	M3/V3 (TW 124631) 31.03.2019
19939	Stabimed® ultra, 4 kg	
18799	Tiutol® dent, 5 l	
9325425	Tiutol® dent, 5 l	