

## SHARING EXPERTISE

B. Braun Medical AG  
Seesatz 17  
6204 Sempach  
Switzerland

**DECLARATION OF CONFORMITY**

<b>Product Category:</b> Solutions and powders for cleaning of dental and surgical instruments and devices, endoscopes, anaesthetic equipment and for use in ultrasonic bathes
--

Brand Name	Dosage form	Date of CE marking/Batch	Remarks
Cleaner N	Solution	15.03.2002	
Helimatic® Cleaner alkaline	Solution	15.03.2002	
Helimatic® Cleaner enzymatic	Solution	15.03.2002	
Helimatic® Cleaner enzymatic NF	Solution	16.11.2017 / Batch 17464M22	
Helimatic® Cleaner MA	Solution	03.05.2013 / Batch 13185M16	
Helimatic® Cleaner neutral	Solution	09.07.2001	
Helimatic® Latriniser	Solution	14.01.2004	
Helimatic® Neutralizer C	Solution	15.03.2002	
Helimatic® Neutralizer forte	Solution	25.11.2004 / Batch 4485M09	
Helimatic® Rinse neutral	Solution	15.03.2002	
Helimatic® Rinse neutral NF	Solution	15.11.2017 / Batch 17463M20	
Helizyme	Solution	09.07.2001	

Article numbers: see attachment

**Conformity Assessment Procedure:** according to ANNEX VII of the COUNCIL DIRECTIVE 93/42/EEC

**Classification:** according to ANNEX IX of the COUNCIL DIRECTIVE 93/42/EEC

**Class / Rule:** Class I (non sterile) / Rule 1

**Applied Standards:** EN ISO 13485:2016, Certificate No. Q5 061585 0030, valid until 31.07.2022

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

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 VII.

Sempach, 05.08.2019

B. Braun Medical AG

  
Peter Egli  
Head of Quality Unit CoE Infection Control

  
Dr. Michael Gluschke  
Director Global Regulatory Affairs OPM

Effective

**DECLARATION OF CONFORMITY**  
**Attachment for Medical Devices Class I**

<b>Art. No.</b>	<b>Product Name</b>	<b>Remarks</b>
3893146	Cleaner N, 1000ml	
18724	Helimatic® Cleaner alkaline, 5 l	
18731	Helimatic® Cleaner alkaline, 5 l	
18774	Helimatic® Cleaner alkaline, 200 l	
18796	Helimatic® Cleaner alkaline, 600 l	
18558	Helimatic® Cleaner enzymatic, 5 l	
18560	Helimatic® Cleaner enzymatic, 200 l	
18740	Helimatic® Cleaner enzymatic, 600 l	
18558	Helimatic Cleaner enzymatic NF, 5 l	
18560	Helimatic Cleaner enzymatic NF, 200 l	
19678	Helimatic® Cleaner MA, 5 l	
19679	Helimatic® Cleaner MA, 10 l	
19680	Helimatic® Cleaner MA, 220 kg	
19681	Helimatic® Cleaner MA, 600 kg	
18519	Helimatic® Cleaner neutral, 5 l	
18521	Helimatic® Cleaner neutral, 200 l	
18823	Helimatic® Latriniser, 5 l	
18824	Helimatic® Latriniser, 5 l	
18944	Helimatic® Latriniser, 200 l	
18725	Helimatic® Neutralizer C, 5 l	
18732	Helimatic® Neutralizer C, 5 l	
18772	Helimatic® Neutralizer C, 200 l	
18798	Helimatic® Neutralizer C, 600 l	
18863	Helimatic® Neutralizer forte, 200 l	
18864	Helimatic® Neutralizer forte, 600 l	
18568	Helimatic® Rinse neutral, 5 l	
19568	Helimatic® Rinse neutral NF, 5 l	
19888	Helimatic® Rinse neutral NF, 10 l	
18557	Helizyme, 1000ml	
18765	Helizyme, 1000ml	
18767	Helizyme, 5 l	
19448	Helizyme, 5 l	
19862	Helizyme, 1000 ml	
19863	Helizyme, 5 l	