

**Konformitätserklärung
Declaration of Conformity**

Wir

We

**B. Braun Medical AG
Seesatz 17
6204 Sempach
Schweiz / Switzerland
SRN: CH-MF-000017781****EU/EC REP
B. Braun Melsungen AG
Carl-Braun-Strasse 1
34212 Melsungen
Deutschland / Germany
SRN: DE-AR-000000202**erklären in eigener Verantwortung,
dass das/die Produkt/e**Helimatic® Cleaner alkaline**
Reiniger zur Medizinproduktaufbereitung
Basis-UDI-DI: 4039239000000052ZF
(Artikelnummer siehe Anlage I)**Helimatic® Cleaner enzymatic NF**
Reiniger zur Medizinproduktaufbereitung
Basis-UDI-DI: 4039239000000053ZH
(Artikelnummern siehe Anlage I)**Helimatic® Cleaner MA**
Reiniger zur Medizinproduktaufbereitung
Basis-UDI-DI: 4039239000000054ZK
(Artikelnummern siehe Anlage I)**Helimatic® Cleaner neutral**
Reiniger zur Medizinproduktaufbereitung
Basis-UDI-DI: 4039239000000055ZM
(Artikelnummern siehe Anlage I)**Helimatic® Latriniser**
Reiniger zur Medizinproduktaufbereitung
Basis-UDI-DI: 4039239000000056ZP
(Artikelnummern siehe Anlage I)**Helimatic® Lubricant**
Lubricant zur Medizinproduktaufbereitung
Basis-UDI-DI: 4039239000000051ZD
(Artikelnummern siehe Anlage I)hereby declare in our sole responsibility
that the product/s**Helimatic® Cleaner alkaline**
Cleaner for reprocessing of medical devices
Basic-UDI-DI: 4039239000000052ZF
(Article number see attachment I)**Helimatic® Cleaner enzymatic NF**
Cleaner for reprocessing of medical devices
Basic-UDI-DI: 4039239000000053ZH
(Article numbers see attachment I)**Helimatic® Cleaner MA**
Cleaner for reprocessing of medical devices
Basic-UDI-DI: 4039239000000054ZK
(Article numbers see attachment I)**Helimatic® Cleaner neutral**
Cleaner for reprocessing of medical devices
Basic-UDI-DI: 4039239000000055ZM
(Article numbers see attachment I)**Helimatic® Latriniser**
Cleaner for reprocessing of medical devices
Basic-UDI-DI: 4039239000000056ZP
(Article numbers see attachment I)**Helimatic® Lubricant**
Lubricant for reprocessing of medical devices
Basic-UDI-DI: 4039239000000051ZD
(Article numbers see attachment I)

Helimatic® Mild Alkaline Cleaner
Reiniger zur Medizinproduktaufbereitung
Basis-UDI-DI: 4039239000000057ZR
(Artikelnummern siehe Anlage I)

Helimatic® Neutralizer C
Reiniger zur Medizinproduktaufbereitung
Basis-UDI-DI: 4039239000000058ZT
(Artikelnummer siehe Anlage I)

Helimatic® Pre Treat Spray
Medizinproduktaufbereitung
Basis-UDI-DI: 4039239000000060ZE
(Artikelnummer siehe Anlage I)

Helimatic® Rinse neutral NF
Reiniger zur Medizinproduktaufbereitung
Basis-UDI-DI: 4039239000000061ZG
(Artikelnummern siehe Anlage I)

Helimatic® Scale and Rust Remover
Medizinproduktaufbereitung
Basis-UDI-DI: 4039239000000062ZJ
(Artikelnummern siehe Anlage I)

Helizyme
Reiniger zur Medizinproduktaufbereitung
Basis-UDI-DI: 4039239000000063ZL
(Artikelnummern siehe Anlage I)

Soft a® Swabs
Reinigungstupfer für die intakte Haut
Basis-UDI-DI: 4039239000000064ZN
(Artikelnummern siehe Anlage I)

mit den Anforderungen der Medizinprodukte
Verordnung (EU) 2017/745 übereinstimmen

Konformitätsbewertungsverfahren
nach Artikel 52 Absatz 7
der oben genannten Verordnung

Klassifizierung
gemäß Anhang VIII der oben genannten
Verordnung
Klasse I, Regel 1

Gültig bis
Gemäß gültigem ISO-Zertifikat,
Nr. Q5 061585 0030 Rev. 03
Gültig bis 31.07.2028

Helimatic® Mild Alkaline Cleaner
Cleaner for reprocessing of medical devices
Basic-UDI-DI: 4039239000000057ZR
(Article numbers see attachment I)

Helimatic® Neutralizer C
Cleaner for reprocessing of medical devices
Basic-UDI-DI: 4039239000000058ZT
(Article number see attachment I)

Helimatic® Pre Treat Spray
Reprocessing of medical devices
Basic-UDI-DI: 4039239000000060ZE
(Article number see attachment I)

Helimatic® Rinse neutral NF
Cleaner for reprocessing of medical devices
Basic-UDI-DI: 4039239000000061ZG
(Article numbers see attachment I)

Helimatic® Scale and Rust Remover
Reprocessing of medical devices
Basic-UDI-DI: 4039239000000062ZJ
(Article numbers see attachment I)

Helizyme
Cleaner for reprocessing of medical devices
Basic-UDI-DI: 4039239000000063ZL
(Article numbers see attachment I)

Soft a® Swabs
Cleansing swabs for intact skin
Basic-UDI-DI: 4039239000000064ZN
(Article numbers see attachment I)

are in conformity with the requirements of the
Medical Device Regulation (EU) 2017/745

Conformity Assessment Procedure
according to article 52 section 7
of the Regulation named above

Classification
according to annex VIII of the Regulation
named above
Class I, Rule 1

Valid until
According to the ISO 13485 Certificate,
No. Q5 061585 0030 Rev. 03
Valid until 31.07.2028

Anlage I / Attachment I

Art.-Nr. Art. No.	Produktname Product name	UDI-DI UDI-DI	Basis-UDI-DI Basic-UDI-DI
18731	Helimatic® Cleaner alkaline, 5 l	7612449081101	4039239000000052ZF
18558	Helimatic® Cleaner enzymatic, 5 l	7612449041556	4039239000000053ZH
18559	Helimatic® Cleaner enzymatic, 10 l	7612449041259	4039239000000053ZH
18560	Helimatic® Cleaner enzymatic, 200 l	7612449079054	4039239000000053ZH
19678	Helimatic® Cleaner MA, 5 l	7612449136207	4039239000000054ZK
19679	Helimatic® Cleaner MA, 10 l	7612449136252	4039239000000054ZK
19680	Helimatic® Cleaner MA, 220 kg	7612449136306	4039239000000054ZK
19766	Helimatic® Cleaner MA, 220 kg	7612449143403	4039239000000054ZK
19681	Helimatic® Cleaner MA, 600 kg	7612449136351	4039239000000054ZK
18519	Helimatic® Cleaner neutral, 5 l	7612449041709	4039239000000055ZM
18797	Helimatic® Cleaner neutral, 600 kg	7612449085659	4039239000000055ZM
18823	Helimatic® Latriniser, 5 l	7612449087905	4039239000000056ZP
18824	Helimatic® Latriniser, 5 l	7612449087950	4039239000000056ZP
19111	Helimatic® Latriniser, 10 l	7612449105203	4039239000000056ZP
180341	Helimatic® Lubricant, 5 l	4046955857142	4039239000000051ZD
180342	Helimatic® Lubricant, 10 l	4046955857128	4039239000000051ZD
180346	Helimatic® Mild Alkaline Cleaner, 5 l	4046955857050	4039239000000057ZR
180347	Helimatic® Mild Alkaline Cleaner, 10 l	4046955857029	4039239000000057ZR
180348	Helimatic® Mild Alkaline Cleaner, 200 l	4046955856800	4039239000000057ZR
18732	Helimatic® Neutralizer C, 5 l	7612449081156	4039239000000058ZT
180335	Helimatic® Neutralizer C, 10 l	4046955847815	4039239000000058ZT
18772	Helimatic® Neutralizer C, 200 l	7612449083853	4039239000000058ZT
180334	Helimatic® Pre Treat Spray	4046955847570	4039239000000060ZE
18568	Helimatic® Rinse neutral, 5 l	7612449131851	4039239000000061ZG
19888	Helimatic® Rinse neutral, 10 l	7612449150159	4039239000000061ZG
18773	Helimatic® Rinse neutral, 200 l	7612449083907	4039239000000061ZG
180339	Helimatic® Scale and Rust Remover, 5 l	4046955856763	4039239000000062ZJ
180340	Helimatic® Scale and Rust Remover, 10 l	4046955857166	4039239000000062ZJ
18557	Helizyme, 1000 ml	7612449078859	4039239000000063ZL
18765	Helizyme, 1000 ml	7612449083204	4039239000000063ZL
18767	Helizyme, 5 l	7612449083402	4039239000000063ZL
19448	Helizyme, 5 l	7612449121654	4039239000000063ZL
19579	Softa® Swabs	7612449128301	4039239000000064ZN

HISTORY OF DOCUMENT

Version	Modification
01	New documenta cc. Regulation (EU) 2017/745
02	EoL Article 18560 deleted – TW 204702
03	SRN: CH-MF and SRN: DE-AR added; Correction of wrong article number 19568 -> 18568
04	Update ISO 13485 Certificate Number & Expiration
05	Addition of articles to Attachment I as some article codes were missing: 18559, 18560, 19111, 180341, 180342, 180346, 180347, 180348, 180335, 18772, 180334, 18773, 180339, 180340
06	Addition of Softa-Swabs as medical device
07	Change of "own responsibility" to "sole"responsibility Update referenced ISO 13485 certificate Addition of "History of Document"

Title: Declaration of Conformity, Class I, MDR Initiator: Jan-Aurel ? Pfister

This document is signed electronically in compliance with the B. Braun electronic signature policies and procedures by following persons:

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Effective