

**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: 4039239000000051ZDhereby declare in our own 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**Effective**

Helimatic® Mild Alkaline Cleaner
Reiniger zur Medizinproduktaufbereitung
Basis-UDI-DI: 4039239000000057ZR

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

Helimatic® Pre Treat Spray
Medizinproduktaufbereitung
Basis-UDI-DI: 4039239000000060ZE

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

Helizyme
Reiniger zur Medizinproduktaufbereitung
Basis-UDI-DI: 4039239000000063ZL
(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
Gültig bis 31.07.2022

Helimatic® Mild Alkaline Cleaner
Cleaner for reprocessing of medical devices
Basic-UDI-DI: 4039239000000057ZR

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

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

Helizyme
Cleaner for reprocessing of medical devices
Basic-UDI-DI: 4039239000000063ZL
(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
Valid until 31.07.2022

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 NF, 5 l	7612449041556	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
18732	Helimatic® Neutralizer C, 5 l	7612449081156	4039239000000058ZT
18568	Helimatic® Rinse neutral NF, 5 l	7612449131851	4039239000000061ZG
19888	Helimatic® Rinse neutral NF, 10 l	7612449150159	4039239000000061ZG
18557	Helizyme, 1000 ml	7612449078859	4039239000000063ZL
18765	Helizyme, 1000 ml	7612449083204	4039239000000063ZL
18767	Helizyme, 5 l	7612449083402	4039239000000063ZL
19448	Helizyme, 5 l	7612449121654	4039239000000063ZL

Document amendment information

Version	Description of the changes
1.0	First issue according to new Regulation (EU) 2017/745 (MDR)
2.0	EoL Article 18560 deleted – TW 204702
3.0	SRN: CH-MF and SRN: DE-AR added; Correction of wrong article number 19568 → 18568

Title: Declaration of Conformity, Class I, MDR Initiator: Sascha ? Kessler

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

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Meaning: Approve Document
