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

hereby declare in our own responsibility
that the product/s

Helimatic® Cleaner alcaline
Reiniger zur Medizinprodukteaufbereitung
Basis-UDI-DI: 4039239000000052ZF
(Artikelnummer siehe Anlage I)

Helimatic® Cleaner alcaline
Cleaner for reprocessing of medical devices
Basic-UDI-DI: 4039239000000052ZF
(Article number see attachment I)

Helimatic® Cleaner enzymatic NF
Reiniger zur Medizinprodukteaufbereitung
Basis-UDI-DI: 4039239000000053ZH
(Artikelnummern siehe Anlage I)

Helimatic® Cleaner enzymatic NF
Cleaner for reprocessing of medical devices
Basic-UDI-DI: 4039239000000053ZH
(Article numbers see attachment I)

Helimatic® Cleaner MA
Reiniger zur Medizinprodukteaufbereitung
Basis-UDI-DI: 4039239000000054ZK
(Artikelnummern siehe Anlage I)

Helimatic® Cleaner MA
Cleaner for reprocessing of medical devices
Basic-UDI-DI: 4039239000000054ZK
(Article numbers see attachment I)

Helimatic® Cleaner neutral
Reiniger zur Medizinprodukteaufbereitung
Basis-UDI-DI: 4039239000000055ZM
(Artikelnummern siehe Anlage I)

Helimatic® Cleaner neutral
Cleaner for reprocessing of medical devices
Basic-UDI-DI: 4039239000000055ZM
(Article numbers see attachment I)

Helimatic® Latriniser
Reiniger zur Medizinprodukteaufbereitung
Basis-UDI-DI: 4039239000000056ZP
(Artikelnummern siehe Anlage I)

Helimatic® Latriniser
Cleaner for reprocessing of medical devices
Basic-UDI-DI: 4039239000000056ZP
(Article numbers see attachment I)

Helimatic® Lubricant
Lubricant zur Medizinprodukteaufbereitung
Basis-UDI-DI: 4039239000000051ZD
(Artikelnummern siehe Anlage I)

Helimatic® Lubricant
Lubricant for reprocessing of medical devices
Basic-UDI-DI: 4039239000000051ZD
(Article numbers see attachment I)

Effective

This document contains information that is the confidential and proprietary property of B. Braun. Any dissemination, distribution or copying of this document is strictly prohibited without the prior written consent of B. Braun. Anyone receiving this document in error should immediately notify B. Braun's Legal Department and return this document to B. Braun Medical AG. Viewed by:if-pim-admin

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

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

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

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

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

Helizyme
Reiniger zur Medizinprodukteaufbereitung
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. 02
Gültig bis 31.07.2025

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. 02
Valid until 31.07.2025

Anlage I / Attachment I

Art.-Nr. Art. No.	Produktname Product name	UDI-DI UDI-DI	Basis-UDI-DI Basic-UDI-DI
18731	Helimatic® Cleaner alcaline, 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	Soft a® Swabs	7612449128301	4039239000000064ZN

Effective

Effective

Title: Declaration of Conformity, Class I, MDR Initiator: Laura ? Idorasi

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

UserName: Idorasi, Laura (idorlaro)
Title: GRA-RO15 Junior Manager GRA Medical Devices Avitum
Date: Wednesday, 05 March 2025, 13:27 W. Europe Daylight Time
Meaning: Document signed as Author
==========

UserName: Gluschke, Michael (glusmich)
Title: Director Global Regulatory Affairs
Date: Wednesday, 05 March 2025, 16:54 W. Europe Daylight Time
Meaning: Approve Document
==========

UserName: Egli, Peter (eglipech)
Title: OM-QM-CH05 - Head of Quality Unit
Date: Thursday, 06 March 2025, 07:25 W. Europe Daylight Time
Meaning: Approve Document
==========