Wir | We

B. Braun Medical AG
Seesatz 17
6204 Sempach
Schweiz / Switzeralnd

EU/EC REP
B. Braun Melsungen AG
Carl-Braun-Strasse 1
34212 Melsungen
Deutschland / Germany

erklären in eigener Verantwortung,
dass die Produkte

Ethanol 70% denat.
Flächendesinfektion von nicht-invasiven Produkten
Basis-UDI-DI: 403923900000087332
(Artikelnummern siehe Anlage I)
Erste Charge nach MDR: 21202M**

Ethanol 70% pure
Flächendesinfektion von nicht-invasiven Produkten
Basis-UDI-DI: 403923900000087434
(Artikelnummern siehe Anlage I)
Erste Charge nach MDR: 21225M14

Ethanol 80% denat.
Flächendesinfektion von nicht-invasiven Produkten
Basis-UDI-DI: 403923900000087536
(Artikelnummern siehe Anlage I)
Erste Charge nach MDR: 21251M**

Helimatic® Cleaner and Disinfectant
Flächendesinfektion von nicht-invasiven Produkten
Basis-UDI-DI: 40392390000009032J
(Artikelnummern siehe Anlage I)
Erste Charge nach MDR: 21254M24

Hexaquart® pure
Flächendesinfektion von nicht-invasiven Produkten
Basis-UDI-DI: 40392390000008793E
(Artikelnummern siehe Anlage I)
Erste Charge nach MDR: 21222M**

hereby declare in our own responsibility
that the products

Ethanol 70% denat.
Surface disinfection of non-invasive medical devices
Basic-UDI-DI: 403923900000087332
(Articles see Attachment I)
First batch acc. MDR: from 21202M**

Ethanol 70% pure
Surface disinfection of non-invasive medical devices
Basic-UDI-DI: 403923900000087434
(Articles see Attachment I)
First batch acc. MDR: 21225M14

Ethanol 80% denat.
Surface disinfection of non-invasive medical devices
Basic-UDI-DI: 403923900000087536
(Articles see Attachment I)
First batch acc. MDR: 21251M**

Helimatic® Cleaner and Disinfectant
Surface disinfection of non-invasive medical devices
Basic-UDI-DI: 40392390000009032J
(Articles see Attachment I)
First batch acc. MDR: 21254M24

Hexaquart® pure
Surface disinfection of non-invasive medical devices
Basic-UDI-DI: 40392390000008793E
(Articles see Attachment I)
First batch acc. MDR: 21222M**

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Meliseptol® acute
Flächendesinfektion von nicht-invasiven Produkten
Basis-UDI-DI: 403923900000088437
(Artikelnummern siehe Anlage I)
Erste Charge nach MDR: 20482M**

Meliseptol® Foam pure
Flächendesinfektion von nicht-invasiven Produkten
Basis-UDI-DI: 40392390000008863B
(Artikelnummern siehe Anlage I)
Erste Charge nach MDR: 21203M**

Meliseptol® pure
Flächendesinfektion von nicht-invasiven Produkten
Basis-UDI-DI: 40392390000008893H
(Artikelnummern siehe Anlage I)
Erste Charge nach MDR: 21223M**

Meliseptol® Wipes sensitive
Flächendesinfektion von nicht-invasiven Produkten
Basis-UDI-DI: 403923900000089134
(Artikelnummern siehe Anlage I)
Erste Charge nach MDR: 21351M09

Meliseptol® Wipes sensitive 100
Flächendesinfektion von nicht-invasiven Produkten
Basis-UDI-DI: 403923900000089236
(Artikelnummern siehe Anlage I)
Erste Charge nach MDR: 21291M01

Meliseptol® Wipes sensitive XL
Flächendesinfektion von nicht-invasiven Produkten
Basis-UDI-DI: 403923900000089236
(Artikelnummern siehe Anlage I)
Erste Charge nach MDR: 21283M20

Meliseptol® acute
Surface disinfection of non-invasive medical devices
Basic-UDI-DI: 403923900000088437
(Articles see Attachment I)
First batch acc. MDR: 20482M**

Meliseptol® Foam pure
Surface disinfection of non-invasive medical devices
Basic-UDI-DI: 40392390000008863B
(Articles see Attachment I)
First batch acc. MDR: 21203M**

Meliseptol® pure
Surface disinfection of non-invasive medical devices
Basic-UDI-DI: 40392390000008893H
(Articles see Attachment I)
First batch acc. MDR: 21223M**

Meliseptol® Wipes sensitive
Surface disinfection of non-invasive medical devices
Basic-UDI-DI: 403923900000089134
(Articles see Attachment I)
First batch acc. MDR: 21351M09

Meliseptol® Wipes sensitive 100
Surface disinfection of non-invasive medical devices
Basic-UDI-DI: 403923900000089236
(Articles see Attachment I)
First batch acc. MDR: 21291M01

Meliseptol® Wipes sensitive XL
Surface disinfection of non-invasive medical devices
Basic-UDI-DI: 403923900000089236
(Articles see Attachment I)
First batch acc. MDR: 21283M20

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

Konformitätsbewertungsverfahren
nach Anhang IX
der oben genannten Verordnung

Klassifizierung
gemäß Anhang VIII
der oben genannten Verordnung
Klasse IIa, Regel 16

Benannte Stelle
TÜV SÜD Product Service GmbH
Kennnummer 0123

Gültig bis
gemäss gültigem EC Zertifikat
G10 061585 0036
bis 14.03.2026

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

Conformity Assessment Procedure
according to annex IX
of the Regulation named above

Classification
according to annex VIII
of the Regulation named above
Class IIa, Rule 16

Notified Body
TÜV SÜD Product Service GmbH
Identification Number 0123

Valid until
according to our valid EC Certificate
G10 061585 0036
until 14.03.2026

Effective

Anlage I / Attachment I

Produktname	Art. Nr.	UDI-DI	Basis UDI-DI
Product name	**Art. No**	**UDI-DI**	**Basic UDI-DI**
Ethanol 70% denat. 500 ml	18676	7612449078750	403923900000087332
Ethanol 70% denat. 1000 ml	18677	7612449078804	403923900000087332
Ethanol 70% denat. 1000 l	18726	7612449080753	403923900000087332
Ethanol 70% denat. 5 l	18791	7612449084850	403923900000087332
Ethanol 70% denat. 1000 ml	18795	7612449085604	403923900000087332
Ethanol 70% denat. 200 l	19296	7612449114960	403923900000087332
Ethanol 70% pure 5 l	18786	7612449084652	403923900000087434
Ethanol 80% denat. 500 ml	18955	7612449097751	403923900000087536
Ethanol 80% denat. 5 l	18958	7612449097904	403923900000087536
Helimatic® Cleaner and Disinfectant	180020	4046955214525	402923900000090 32J
Hexaquart® pure 1000 ml	19942	7612449155154	40392390000008793E
Hexaquart® pure 1000 ml	180028	7612449155703	40392390000008793E
Hexaquart® pure 5 l	19943	7612449155208	40392390000008793E
Hexaquart® pure 5 l	180029	7612449155758	40392390000008793E
Meliseptol® acute 250 ml	180241	4046955637102	403923900000088437
Meliseptol® acute 250 ml	180242	4046955637133	403923900000088437
Meliseptol® acute 750 ml	180243	4046955637386	403923900000088437
Meliseptol® acute 1000 ml	180244	4046955637164	403923900000088437
Meliseptol® acute 5 l	180245	4046955637195	403923900000088437
Meliseptol® acute 250 ml	180246	4046955637218	403923900000088437
Meliseptol® acute 250 ml	180247	4046955637249	403923900000088437
Meliseptol® acute 750 ml	180248	4046955638215	403923900000088437
Meliseptol® acute 1000 ml	180249	4046955637270	403923900000088437
Meliseptol® acute 5 l	180250	4046955637300	403923900000088437
Meliseptol® Foam pure 750 ml	19796	7612449145001	40392390000008863B
Meliseptol® Foam pure 750 ml	19797	7612449145056	40392390000008863B
Meliseptol® Foam pure 750 ml	19804	7612449145308	40392390000008863B
Meliseptol® Foam pure 1000 ml	19469	7612449122453	40392390000008863B
Meliseptol® Foam pure 5 l	19288	7612449114908	40392390000008863B
Meliseptol® Foam pure 5 l	19289	7612449119651	40392390000008863B
Meliseptol® pure 250 ml	19926	7612449152153	40392390000008893H
Meliseptol® pure 1000 ml	19927	7612449152207	40392390000008893H
Meliseptol® pure 5 l	19958	7612449153952	40392390000008893H
Meliseptol® Wipes sensitive refill	19530	7612449128653	403923900000089134
Meliseptol® Wipes sensitive box	19582	7612449128608	403923900000089134
Meliseptol® Wipes sensitive 100	180139	4046955328093	403923900000089236

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Produktname	**Art. Nr.**	**UDI-DI**	**Basis UDI-DI**
Product name	**Art. No**	**UDI-DI**	**Basic UDI-DI**
Meliseptol® Wipes sensitive 100	19894	7612449150456	403923900000089236
Meliseptol® Wipes sensitive XL	19893	7612449150401	403923900000089236

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Title: Declaration of Conformity, Class IIa, 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: Document signed as Author
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Date: Sunday, 21 November 2021, 16:28 W. Europe Daylight Time
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UserName: Gluschke, Michael (glusmich)
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