Wir | We

B. Braun Medical AG
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Schweiz / Switzeralnd
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 die Produkte

Ethanol 70% denat.
Flächendesinfektion von nicht-invasiven Produkten
Basis-UDI-DI: 403923900000087332
(Artikelnummern siehe Anlage I)
Erste Charge nach MDR: 21225M14

Ethanol 70% pure
Flächendesinfektion von nicht-invasiven Produkten
Basis-UDI-DI: 403923900000087434
(Artikelnummern siehe Anlage I)
Erste Charge nach MDR: 22264M27

Ethanol 80% denat.
Flächendesinfektion von nicht-invasiven Produkten
Basis-UDI-DI: 403923900000087536
(Artikelnummern siehe Anlage I)
Erste Charge nach MDR: 21254M25

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: 21365M27

hereby declare in our sole 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 21225M14

Ethanol 70% pure
Surface disinfection of non-invasive medical devices
Basic-UDI-DI: 403923900000087434
(Articles see Attachment I)
First batch acc. MDR: 22264M27

Ethanol 80% denat.
Surface disinfection of non-invasive medical devices
Basic-UDI-DI: 403923900000087536
(Articles see Attachment I)
First batch acc. MDR: 21254M25

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: 21365M27

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Meliseptol® acute
Flächendesinfektion von nicht-invasiven Produkten
Basis-UDI-DI: 403923900000088437
(Artikelnummern siehe Anlage I)
Erste Charge nach MDR: 20482M13

Meliseptol® acute Wipes 100
Flächendesinfektion von nicht-invasiven Produkten
Basis-UDI-DI: 40392390000024222B
(Artikelnummern siehe Anlage I)
Erste Charge nach MDR: 21401M03

Meliseptol® acute Wipes XL
Flächendesinfektion von nicht-invasiven Produkten
Basis-UDI-DI: 40392390000024222B
(Artikelnummern siehe Anlage I)
Erste Charge nach MDR: 22351M09

Meliseptol® Foam pure
Flächendesinfektion von nicht-invasiven Produkten
Basis-UDI-DI: 40392390000008863B
(Artikelnummern siehe Anlage I)
Erste Charge nach MDR: 21203M22

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

Meliseptol® HBV Tissues
Flächendesinfektion von nicht-invasiven Produkten
Basis-UDI-DI: 40392390000008873D
(Artikelnummern siehe Anlage I)
Erste Charge nach MDR: 24201M08

Meliseptol® pure
Flächendesinfektion von nicht-invasiven Produkten
Basis-UDI-DI: 40392390000008893H
(Artikelnummern siehe Anlage I)
Erste Charge nach MDR: 21242M09

Meliseptol® rapid
Flächendesinfektion von nicht-invasiven Produkten
Basis-UDI-DI: 403923900000089032
(Artikelnummern siehe Anlage I)
Erste Charge nach MDR: 24223M15

Meliseptol® acute
Surface disinfection of non-invasive medical devices
Basic-UDI-DI: 403923900000088437
(Articles see Attachment I)
First batch acc. MDR: 20482M13

Meliseptol® acute Wipes 100
Surface disinfection of non-invasive medical devices
Basic-UDI-DI: 40392390000024222B
(Articles see Attachment I)
First batch acc. MDR: 21401M03

Meliseptol® acute Wipes XL
Surface disinfection of non-invasive medical devices
Basic-UDI-DI: 40392390000024222B
(Articles see Attachment I)
First batch acc. MDR: 22351M09

Meliseptol® Foam pure
Surface disinfection of non-invasive medical devices
Basic-UDI-DI: 40392390000008863B
(Articles see Attachment I)
First batch acc. MDR: 21203M22

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

Meliseptol® HBV Tissues
Surface disinfection of non-invasive medical devices
Basic-UDI-DI: 40392390000008873D
(Articles see Attachment I)
First batch acc. MDR: 24201M08

Meliseptol® pure
Surface disinfection of non-invasive medical devices
Basic-UDI-DI: 40392390000008893H
(Articles see Attachment I)
First batch acc. MDR: 21242M09

Meliseptol® rapid
Surface disinfection of non-invasive medical devices
Basic-UDI-DI: 403923900000089032
(Articles see Attachment I)
First batch acc. MDR: 24223M15

Effective

Surface Quick (=Meliseptol® rapid)
Flächendesinfektion von nicht-invasiven Produkten
Basis-UDI-DI: 403923900000089032
(Artikelnummern siehe Anlage I)
Erste Charge nach MDR: 24223M15

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

Softa® Cloth CHX 2%
Flächendesinfektion von nicht-invasiven Produkten
Basis-UDI-DI: 40392390000008963E
(Artikelnummern siehe Anlage I)
Erste Charge nach MDR: 231101

Stabimed® fresh
Lösung für die Instrumentendesinfektion von zahnmedizinischen und chirurgischen Instrumenten und invasiven Medizinprodukten vor Sterilisation
Basis-UDI-DI: 40392390000009112H
(Artikelnummern siehe Anlage I)
Erste Charge nach MDR: tbd

Instrument Forte+ (=Stabimed® fresh)
Lösung für die Instrumentendesinfektion von zahnmedizinischen und chirurgischen Instrumenten und invasiven Medizinprodukten vor Sterilisation
Basis-UDI-DI: 40392390000009112H
(Artikelnummern siehe Anlage I)
Erste Charge nach MDR: tbd

Surface Quick (=Meliseptol® rapid)
Surface disinfection of non-invasive medical devices
Basic-UDI-DI: 403923900000089032
(Articles see Attachment I)
First batch acc. MDR: 24223M15

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

Softa® Cloth CHX 2%
Surface disinfection of non-invasive medical devices
Basic-UDI-DI: 40392390000008963E
(Articles see Attachment I)
First batch acc. MDR: 231101

Stabimed® fresh
Solution for instrument disinfection of dental and surgical instruments and invasive medical devices prior to sterilization
Basic-UDI-DI: 40392390000009112H
(Articles see Attachment I)
First batch acc. MDR: tbd

Instrument Forte+ (=Stabimed® fresh)
Solution for instrument disinfection of dental and surgical instruments and invasive medical devices prior to sterilization
Basic-UDI-DI: 40392390000009112H
(Articles see Attachment I)
First batch acc. MDR: tbd

Uro-Tainer® NaCl 0.9%
Sterile Spüllösung für Urinkatheter
Basis-UDI-DI: 40392390000008983J
(Artikelnummern siehe Anlage I)
Erste Charge nach MDR: tbd

Uro-Tainer® Solutio R
Sterile Spüllösung für Urinkatheter
Basis-UDI-DI: 40392390000008993L
(Artikelnummern siehe Anlage I)
Erste Charge nach MDR: tbd

Uro-Tainer® Suby G
Sterile Spüllösung für Urinkatheter
Basis-UDI-DI: 40392390000009002C
(Artikelnummern siehe Anlage I)
Erste Charge nach MDR: tbd

Uro-Tainer® M NaCl 0.9%
Sterile Spüllösung für Urinkatheter
Basis-UDI-DI: 40392390000008973G
(Artikelnummern siehe Anlage I)
Erste Charge nach MDR: tbd

Uro-Tainer® Twin Solutio R
Sterile Spüllösung für Urinkatheter
Basis-UDI-DI: 40392390000009012E
(Artikelnummern siehe Anlage I)
Erste Charge nach MDR: tbd

Uro-Tainer® Twin Suby G
Sterile Spüllösung für Urinkatheter
Basis-UDI-DI: 40392390000009022G
(Artikelnummern siehe Anlage I)
Erste Charge nach MDR: tbd

Uro-Tainer® NaCl 0.9%
Sterile urinary catheter irrigation solution
Basic-UDI-DI: 40392390000008983J
(Articles see Attachment I)
First batch acc. MDR: tbd

Uro-Tainer® Solutio R
Sterile urinary catheter irrigation solution
Basic-UDI-DI: 40392390000008993L
(Articles see Attachment I)
First batch acc. MDR: tbd

Uro-Tainer® Suby G
Sterile urinary catheter irrigation solution
Basic-UDI-DI: 40392390000009002C
(Articles see Attachment I)
First batch acc. MDR: tbd

Uro-Tainer® M NaCl 0.9%
Sterile urinary catheter irrigation solution
Basic-UDI-DI: 40392390000008973G
(Articles see Attachment I)
First batch acc. MDR: tbd

Uro-Tainer® Twin Solutio R
Sterile urinary catheter irrigation solution
Basic-UDI-DI: 40392390000009012E
(Articles see Attachment I)
First batch acc. MDR: tbd

Uro-Tainer® Twin Suby G
Sterile urinary catheter irrigation solution
Basic-UDI-DI: 40392390000009022G
(Articles see Attachment I)
First batch acc. MDR: tbd

Effective

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

Benannte Stelle
TÜV SÜD Product Service GmbH
Kennnummer 0123

Gültig bis
gemäss gültigem EC Zertifikat
G10 061585 0036 Rev. 03
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

Notified Body
TÜV SÜD Product Service GmbH
Identification Number 0123

Valid until
according to our valid EC Certificate
G10 061585 0036 Rev. 03
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 5 l	180343	4046955857104	40392390000009032J
Helimatic® Cleaner and Disinfectant 10 l	180344	4046955857081	40392390000009032J
Helimatic® Cleaner and Disinfectant 200 l	180345	4046955857074	40392390000009032J
Helimatic® Cleaner and Disinfectant 600 l	180388	4046955870448	40392390000009032J
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® acute Wipes 100	180255	4046955661985	40392390000024222B
Meliseptol® acute Wipes 100	180296	4046955716838	40392390000024222B
Meliseptol® acute Wipes XL	180256	4046955661954	40392390000024222B
Meliseptol® acute Wipes XL	180297	4046955716869	40392390000024222B
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

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Produktname	Art. Nr.	UDI-DI	Basis UDI-DI
Product name	**Art. No**	**UDI-DI**	**Basic UDI-DI**
Meliseptol® Foam pure 5 l	19289	7612449119651	40392390000008863B
Meliseptol® Foam pure 750 ml	180197	4046955601127	40392390000008863B
Surface Foam 5 l (=Meliseptol® Foam pure)	19206	4046955633791	40392390000008863B
Surface Foam 750 ml (=Meliseptol® Foam pure)	19990	4046955633814	40392390000008863B
Meliseptol® HBV Tissues, Box	18706	7612449080500	40392390000008873D
Meliseptol® HBV Tissues, Refill	18707	7612449080555	40392390000008873D
Meliseptol® HBV Tissues, Box	19096	7612449104107	40392390000008873D
Meliseptol® HBV Tissues, Refill	19097	7612449118418	40392390000008873D
Meliseptol® pure 1000 ml	19927	7612449152207	40392390000008893H
Meliseptol® pure 5 l	19958	7612449153952	40392390000008893H
Meliseptol® pure 250 ml	180397	4046955875320	40392390000008893H
Meliseptol® pure 1000 ml	180398	4046955875245	40392390000008893H
Meliseptol® pure 1000 ml	180399	4046955875290	40392390000008893H
Meliseptol® pure 1000 ml	180400	4046955875214	40392390000008893H
Meliseptol® pure 5 l	180401	4046955875276	40392390000008893H
Meliseptol® rapid 250 ml	18564	7612449043055	403923900000089032
Meliseptol® rapid 1000 ml	18565	7612449043253	403923900000089032
Meliseptol® rapid 250 ml	18566	7612449043505	403923900000089032
Meliseptol® rapid 5 l	18567	7612449043550	403923900000089032
Meliseptol® rapid 250 ml	19047	7612449102257	403923900000089032
Meliseptol® rapid 1000 ml	19048	7612449102301	403923900000089032
Meliseptol® rapid 5 l	19049	7612449102356	403923900000089032
Meliseptol® rapid 1000 ml	19108	7612449105050	403923900000089032
Meliseptol® rapid 750 ml	19912	7612449151507	403923900000089032
Surface Quick 5 l (=Meliseptol® rapid)	19208	4046955633838	403923900000089032
Meliseptol® Wipes sensitive refill	19530	7612449128653	403923900000089134
Meliseptol® Wipes sensitive box	19582	7612449128608	403923900000089134
Meliseptol® Wipes sensitive 100	19894	7612449150456	403923900000089236
Meliseptol® Wipes sensitive XL	19893	7612449150401	403923900000089236
Softa® Cloth CHX 2%	19581	7612449128554	40392390000008963E
Stabimed® fresh 1000 ml	19689	7612449137105	40392390000009112H
Stabimed® fresh 1000 ml	19829	7612449146855	40392390000009112H
Stabimed® fresh 5 l	19690	7612449137150	40392390000009112H
Stabimed® fresh 5 l	19828	7612449146909	40392390000009112H
Instrument Forte+ (=Stabimed® fresh) 5 l	19916	4046955633746	40392390000009112H
Uro-Tainer NaCl 0.9%	FB99849	4046964085437	40392390000008983J
Uro-Tainer NaCl 0.9%	FB99881	4046964085529	40392390000008983J
Uro-Tainer NaCl 0.9%	FB99833	4030539020209	40392390000008983J

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Produktname	Art. Nr.	UDI-DI	Basis UDI-DI
Product name	**Art. No**	**UDI-DI**	**Basic UDI-DI**
Uro-Tainer NaCl 0.9%	FB99882	4046964085543	40392390000008983J
Uro-Tainer Solutio R	FB99843	4046964085413	40392390000008993L
Uro-Tainer Solutio R	FB99841	4046964085406	40392390000008993L
Uro-Tainer Solutio R	FB99894	4046964085567	40392390000008993L
Uro-Tainer Suby G	FB99851	4046964085451	40392390000009002C
Uro-Tainer Suby G	FB99839	4030539051477	40392390000009002C
Uro-Tainer M NaCl 0.9%	FB99854	4030539051446	40392390000008973G
Uro-Tainer M NaCl 0.9%	FB99853	4030539029186	40392390000008973G
Uro-Tainer Twin Solutio R	9746625	4030539048958	40392390000009012E
Uro-Tainer Twin Suby G	9746609	4030539048316	40392390000009022G

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HISTORY OF DOCUMENT

Version	Modification
01	New document acc. Regulation (EU) 2017/745; MDR pilot dossier (Meliseptol® Wipes Sensitive) transferred from DoC acc. MDD; New article numbers Meliseptol® acute added.
02	Hexaquart® pure added.
03	Meliseptol® Foam pure, Meliseptol® pure, Meliseptol® Wipes sensitive 100, Meliseptol® Wipes sensitive XL added.
04	Ethanol 70% denat., Ethanol 70% pure, Ethanol 80% denat, Helimatic® Cleaner and Disinfectant added.
05	Meliseptol® acute CE articles (180246, 180247, 180248, 180249, 180250) added.
06	SRN added
07	Meliseptol® acute Wipes 100 articles (180255, 180296) added.
08	First batch acc. MDR corrected for Meliseptol® acute Wipes 100.
09	Meliseptol® acute Wipes XL articles (180256, 180297) added; First batch acc. MDR corrected for: Ethanol 70% denat., Ethanol 70% pure, Ethanol 80% denat, Hexaquart® pure, Meliseptol® acute, Meliseptol® Foam pure, Meliseptol® pure; Rev. 00 added to EC Certificate G10 061585 0036
10	Softa® Cloth (article 19581) added; Helimatic® Cleaner and Disinfectant articles (180344, 180345) added
11	Meliseptol® HBV Tissues and Meliseptol® rapid added.
12	Meliseptol® Pure articles (180397, 180398, 180399, 180400, 180401) added.
13	G10 061585 0036 Rev. updated from 00 to 02.
14	Uro-Tainer® NaCl 0.9%, Uro-Tainer® Solutio R, Uro-Tainer® Suby G, Uro-Tainer® M NaCl 0.9%, Uro-Tainer® Twin Solutio R, Uro-Tainer® Twin Suby G added; G10 061585 0036 Rev. updated to 03
15	Stabimed® fresh and Instrument Forte+ (=Stabimed® fresh) added; Surface Quick (=Meliseptol® rapid) added; Helimatic® Cleaner and Disinfectant 5 l Art. No. and UDI-DI corrected; Meliseptol® Pure 250 ml (article 19926) removed
16	Meliseptol® Foam Pure article 180197 added.
17	"own" (responsibility) corrected to "sole".
18	Surface Foam (=Meliseptol® Foam pure) articles (19206, 19990) added
19	Correction of Basic UDI-DI number of Helimatic® Cleaner and Disinfectant in attachment I; History of Document added
20	Deletion of articles 19915 and 180139; addition of new article 180388 Helimatic® Cleaner and Disinfectant

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Title: Declaration of Conformity, Class IIa, MDR Initiator: Marina ? Stiefel Berman

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Meaning: Document signed as Author
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UserName: Egli, Peter (eglipech)
Title: OM-QM-CH05 - Head of Quality Unit
Date: Thursday, 28 August 2025, 07:59 W. Europe Daylight Time
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