

B. Braun Medical AG
 Seesatz 17
 6204 Sempach
 Switzerland

DECLARATION OF CONFORMITY

Product Category: Solutions and tissues for surface disinfection of medical equipment, e.g. operating accessories, hospital beds and treatment chairs

Brand Name	Dosage form	Date of CE marking/Batch no.	Remarks
Ethanol 70 % pure / denat.	Solution	03.02.2003	
Ethanol 80 % denat.	Solution	12.07.2005 / Batch 5273M08	
Hexaquant® forte	Solution	19.12.2006 / Batch 6513M04	EoL 9-2018 / TW 142212
Hexaquant® plus	Solution	01.02.1998	
Hexaquant® plus lemon fresh	Solution	15.11.2002	
Hexaquant® pure	Solution	05.07.2018 / Batch 18274M18	
Hexaquant® S/ Hexaquant® S, perfumed	Solution	22.07.2002	
Hexaquant® XL	Solution	17.08.2018 / Batch 18335M02	
Meliseptol®	Solution	01.02.1998	EoL 4-2016 / TW 95774
Meliseptol® pure	Solution	29.03.2017 / Batch 17133M08	
Meliseptol® NEW FORMULA	Solution	10.12.2014 / Batch 14502M24	
Meliseptol® Foam pure	Solution	17.09.2007 / Batch 7381M06	NoC 713063241 Batch 15271M35A
Meliseptol® HBV Tücher / Tissues	Tissues	02.10.2001	NoC 140708 Batch 14393M19
Meliseptol® rapid	Solution	11.05.2000	NoC 713092451 Batch 17065M41V
Meliseptol® Wipes sensitive	Wipes	29.06.2011 / Batch 11231M02	
Meliseptol® Wipes sensitive XL	Wipes	11.07.2016 / Batch 16215M19	
Meliseptol® Wipes sensitive 100	Wipes	06.07.2016 / Batch 16221M08	
Melsept® SF	Solution	01.02.1998	
Melsept® Spray	Solution	27.03.2012 / Batch 12132M07	EoL 11-2018 / TW 146913
Melsitt®	Solution	01.02.1998	
Softa® Cloth CHX 2%	Wipes	20.12.2011 / Batch 1347720	

Article numbers: see next pages

Conformity Assessment Procedure according to ANNEX II excluding (4) of the COUNCIL DIRECTIVE 93/42/EEC

Classification according to ANNEX IX of the COUNCIL DIRECTIVE 93/42/EEC

Class / Rule Class IIa / Rule 15

Applied Standards EN ISO 13485:2016, Certificate No. Q5 18 05 61585 027, valid until 31.07.2019

EC Certificate No. G1 16 05 61585 017; valid until 17.05.2019

Notified Body TÜV SÜD Product Service GmbH, Zertifizierstelle, Ridlerstrasse 65, 80339 München, Germany

Identification no. 0123

**DECLARATION OF CONFORMITY
Medical Devices Class IIa**

We herewith declare under our sole responsibility that the above mentioned products meet all the provisions of the COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices as amended by Directive 2007/47/EC, which apply to them, as stated in ANNEX II.

Sempach, 14.01.2019

B. Braun Medical AG



Peter Egli
Head of Quality Unit CoE Infection Control



Dr. Michael Gluschke
Director Global Regulatory Affairs OPM

DECLARATION OF CONFORMITY
Medical Devices Class IIa

Art. No.	Product Name	Remarks
18676	Ethanol 70 % denat., 500 ml	
18677	Ethanol 70 % denat., 1000 ml	
18791	Ethanol 70 % denat., 5 l	
18795	Ethanol 70 % denat., 1000 ml	
19296	Ethanol 70 % denat., 200 l	
19756	Ethanol 70 % denat., 500 ml	
18726	Ethanol 70 % denat., 1000 l	
18786	Ethanol 70 % pure, 5 l	
18955	Ethanol 80% denat., 500 ml	
18958	Ethanol 80% denat., 5 l	
19105	Hexaquart® forte, 1000 ml	M3/V3 / EoL – TW136562 / 4-21
19106	Hexaquart® forte, 5 l	M3/V3 / EoL – TW136562 / 7-21
19379	Hexaquart® forte, 5 l	M3/V3 / EoL – TW136562 / 7-21
18884	Hexaquart® plus, 1000 ml	
18885	Hexaquart® plus, 5 l	
18887	Hexaquart® plus, 200 l	
19081	Hexaquart® plus, 1000 ml	
19083	Hexaquart® plus, 5 l	
18784	Hexaquart® plus lemon fresh, 1000 ml	
18785	Hexaquart® plus lemon fresh, 5 l	
18918	Hexaquart® plus lemon fresh, 200 l	
19841	Hexaquart® plus lemon fresh, 1000 ml	
19942	Hexaquart® pure, 1000 ml	
19943	Hexaquart® pure, 5 l	
180028	Hexaquart® pure, 1000 ml	
180029	Hexaquart® pure, 5 l	
18442	Hexaquart® S, 1000 ml	
19928	Hexaquart S perfumed, 10 l	
2587955	Hexaquart® S perfumed, 5 l	M3/V3 / EoL – TW 106939 / 10-20
2587963	Hexaquart® S perfumed, 25 l	M3/V3 / EoL – TW 128099 / 3-21
19940	Hexaquart® XL, 1000 ml	
19941	Hexaquart® XL, 5 l	
180026	Hexaquart® XL, 1000 ml	
180027	Hexaquart® XL, 5 l	
18353	Meliseptol®, 200 l	M3/V3 / EoL – TW 95774 / 1-21
18888	Meliseptol®, 250 ml	M3/V3 / EoL – TW 95774 / 1-21
18889	Meliseptol®, 1000 ml	M3/V3 / EoL – TW 95774 / 1-21
18890	Meliseptol®, 1000 ml	M3/V3 / EoL – TW 95774 / 1-21
18891	Meliseptol®, 5 l	M3/V3 / EoL – TW 95774 / 1-21
18893	Meliseptol®, 600 l	M3/V3 / EoL – TW 95774 / 1-21
19043	Meliseptol®, 1000 ml	M3/V3 / EoL – TW 95774 / 1-21
19044	Meliseptol®, 1000 ml	M3/V3 / EoL – TW 95774 / 1-21
19045	Meliseptol®, 5 l	M3/V3 / EoL – TW 95774 / 1-21
19288	Meliseptol® Foam pure, 5 l	
19289	Meliseptol® Foam pure, 5 l	
19469	Meliseptol® Foam pure, 1000 ml	
19598	Meliseptol® Foam pure, 5 l	
19796	Meliseptol® Foam pure, 750 ml	
19797	Meliseptol® Foam pure, 750 ml	
19804	Meliseptol® Foam pure, 750 ml	

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Medical Devices Class IIa

Art. No.	Product Name	Remarks
18706	Meliseptol® HBV Tissues, Box	
18707	Meliseptol® HBV Tissues, Refill	
19096	Meliseptol® HBV Tissues, Box	
19097	Meliseptol® HBV Tissues, Refill	
19757	Meliseptol® New Formula, 200 l	
19758	Meliseptol® New Formula, 5 l	
19760	Meliseptol® New Formula, 1000 l	
19761	Meliseptol® New Formula, 1000 ml	
19762	Meliseptol® New Formula, 250 ml	
19763	Meliseptol® New Formula, 250 ml	
19764	Meliseptol® New Formula, 1000 ml	
180077	Meliseptol® New Formula, 500 ml	
180077	Meliseptol® New Formula, 500 ml	
19926	Meliseptol® pure, 250 ml	
19927	Meliseptol® pure, 1000 ml	
19958	Meliseptol® pure, 5 l	
18564	Meliseptol® rapid, 250 ml	
18565	Meliseptol® rapid, 1000 ml	
18566	Meliseptol® rapid, 250 ml	
18567	Meliseptol® rapid, 5 l	
18583	Meliseptol® rapid, 25 l	M3/V3 / EoL – TW 128099 / 1-21
18693	Meliseptol® rapid, 200 l	
19047	Meliseptol® rapid, 250 ml	
19048	Meliseptol® rapid, 1000 ml	
19049	Meliseptol® rapid, 5 l	
19108	Meliseptol® rapid, 1000 ml	
19172	Meliseptol® rapid, 750 ml	M3/V3 / EoL – TW 114178 / 10-21
19912	Meliseptol® rapid, 750 ml	
19530	Meliseptol® Wipes sensitive, Refill	
19582	Meliseptol® Wipes sensitive, Box	
19867	Meliseptol® Wipes sensitive, Box	M2/V1
19868	Meliseptol® Wipes sensitive, Refill	M2/V1
19894	Meliseptol® Wipes sensitive 100	
180096	Meliseptol® Wipes sensitive 100	
19893	Meliseptol® Wipes sensitive XL	
18906	Melsept® SF, 1000 ml	
18907	Melsept® SF, 5 l	
18909	Melsept® SF, 200 l	
18910	Melsept® SF, 600 l	
19077	Melsept® SF, 1000 ml	
19078	Melsept® SF, 5 l	
18954	Melsept® Spray, 1000 ml	
18898	Melsitt®, 5 l	M3/V3 / EoL – TW 146913/ 1-22
18900	Melsitt®, 200 l	M3/V3 / EoL – TW 146913/ 12-20
19581	Softa® Cloth CHX 2%	