

DECLARATION OF CONFORMITY

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

Product 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® pure	Solution	05.07.2018 / Batch 18274M18	
Hexaquant® S / Hexaquant® S perfumed	Solution	22.07.2002	EoL / 10-2019 / TW 162574
Hexaquant® XL	Solution	17.08.2018 / Batch 18335M02	
Meliseptol® NEW FORMULA	Solution	10.12.2014 / Batch 14502M24	
Meliseptol® pure	Solution	29.03.2017 / Batch 17133M08	
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 20	Wipes	08.03.2019 / Batch 19094M27	
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	
Softa® Cloth CHX 2%	Wipes	20.12.2011 / Batch 1347720	

DECLARATION OF CONFORMITY
Medical Devices Class IIa

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 061585 0030, valid until 31.07.2022
EC Certificate	No. G1 061585 0032; valid until 17.05.2024
Notified Body	TÜV SÜD Product Service GmbH, Zertifizierstelle, Ridlerstrasse 65, 80339 München, Germany
Identification no.	0123
EC REP	B. Braun Melsungen AG, Carl-Braun-Strasse 1, 34212 Melsungen, Germany

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, 17.05.2021

B. Braun Medical AG



Peter Egli
Head of Quality Management
CoE Infection Prevention & Renal Fluids



Dr. Michael Gluschke
Director Global Regulatory Affairs
CoE Infection Prevention & Renal Fluids

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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	
19106	Hexaquart® forte, 5 l	M3/V3 / EoL – TW136562 / 7-21
19379	Hexaquart® forte, 5 l	M3/V3 / EoL – TW136562 / 7-21
19942	Hexaquart® pure, 1000 ml	
19943	Hexaquart® pure, 5 l	
180028	Hexaquart® pure, 1000 ml	
180029	Hexaquart® pure, 5 l	
19940	Hexaquart® XL, 1000 ml	
19941	Hexaquart® XL, 5 l	
180026	Hexaquart® XL, 1000 ml	
180027	Hexaquart® XL, 5 l	
19288	Meliseptol® Foam pure, 5 l	
19289	Meliseptol® Foam pure, 5 l	
19206	Surface Foam, 5 l	=Meliseptol® Foam pure
19469	Meliseptol® Foam pure, 1000 ml	
19796	Meliseptol® Foam pure, 750 ml	
19797	Meliseptol® Foam pure, 750 ml	
19804	Meliseptol® Foam pure, 750 ml	
19990	Surface Foam, 750 ml	=Meliseptol® Foam pure

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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	M3/V3 / EoL – TW 203274 / 06-21
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	
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	
19208	Surface Quick, 5 l	= Meliseptol® rapid
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	
180104	Meliseptol® Wipes sensitive 20	
19894	Meliseptol® Wipes sensitive 100	
180070	Surface Foam Wipes	= Meliseptol® Wipes sensitive
19893	Meliseptol® Wipes sensitive XL	
18906	Melsept® SF, 1000 ml	
18907	Melsept® SF, 5 l	
18909	Melsept® SF, 200 l	
19077	Melsept® SF, 1000 ml	
19078	Melsept® SF, 5 l	
18954	Melsept® Spray, 1000 ml	
19581	Softa® Cloth CHX 2%	