

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/<br>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® 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<br>Batch 15271M35A |
| Meliseptol® HBV Tücher / Tissues        | Tissues     | 02.10.2001                   | NoC 140708<br>Batch 14393M19     |
| Meliseptol® rapid                       | Solution    | 11.05.2000                   | NoC 713092451<br>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  | 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 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

**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, 05.08.2019

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**

| <b>Art. No.</b> | <b>Product Name</b>                  | <b>Remarks</b>                  |
|-----------------|--------------------------------------|---------------------------------|
| 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           | Hexaquant® forte, 1000 ml            | M3/V3 / EoL – TW136562 / 4-21   |
| 19106           | Hexaquant® forte, 5 l                | M3/V3 / EoL – TW136562 / 7-21   |
| 19379           | Hexaquant® forte, 5 l                | M3/V3 / EoL – TW136562 / 7-21   |
| 18884           | Hexaquant® plus, 1000 ml             |                                 |
| 18885           | Hexaquant® plus, 5 l                 |                                 |
| 18887           | Hexaquant® plus, 200 l               |                                 |
| 19081           | Hexaquant® plus, 1000 ml             |                                 |
| 19083           | Hexaquant® plus, 5 l                 |                                 |
| 18784           | Hexaquant® plus lemon fresh, 1000 ml |                                 |
| 18785           | Hexaquant® plus lemon fresh, 5 l     |                                 |
| 18918           | Hexaquant® plus lemon fresh, 200 l   |                                 |
| 19841           | Hexaquant® plus lemon fresh, 1000 ml |                                 |
| 19942           | Hexaquant® pure, 1000 ml             |                                 |
| 19943           | Hexaquant® pure, 5 l                 |                                 |
| 180028          | Hexaquant® pure, 1000 ml             |                                 |
| 180029          | Hexaquant® pure, 5 l                 |                                 |
| 18442           | Hexaquant® S, 1000 ml                |                                 |
| 19928           | Hexaquant S perfumed, 10 l           |                                 |
| 2587955         | Hexaquant® S perfumed, 5 l           | M3/V3 / EoL – TW 106939 / 10-20 |
| 2587963         | Hexaquant® S perfumed, 25 l          | M3/V3 / EoL – TW 128099 / 3-21  |
| 19940           | Hexaquant® XL, 1000 ml               |                                 |
| 19941           | Hexaquant® XL, 5 l                   |                                 |
| 180026          | Hexaquant® XL, 1000 ml               |                                 |
| 180027          | Hexaquant® 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        |                                 |

**DECLARATION OF CONFORMITY**  
**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    |                                 |
| 180104   | Meliseptol® Wipes sensitive 20      |                                 |
| 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%                 |                                 |