

B. Braun Medical AG
Seesatz 17
6204 Sempach
Switzerland

DECLARATION OF CONFORMITY

Product Category: Sterile urinary catheter irrigation solutions

| Product (Name, Type) | Size | Date of CE marking ¹ / Batch No. | Remarks |
|----------------------------|--------|--|---------|
| Uro-Tainer® NaCl 0.9% | 50 ml | 09.09.2010 | |
| | 100 ml | 09.09.2010 | |
| Uro-Tainer® M NaCl 0.9% | 50 ml | 09.09.2010 | |
| | 100 ml | 09.09.2010 | |
| Uro-Tainer® Suby G | 50 ml | 09.09.2010 | |
| | 100 ml | 09.09.2010 | |
| Uro-Tainer® Twin Suby G | 60 ml | 09.09.2010 | |
| Uro-Tainer® Solutio R | 50 ml | 09.09.2010 | |
| | 100 ml | 09.09.2010 | |
| Uro-Tainer® Twin Solutio R | 60 ml | 09.09.2010 | |

¹Date of first production under responsibility of B. Braun Medical AG, Seesatz 17, CH-6204 Sempach.

Article numbers: see attachment

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|--|--|
| Conformity Assessment Procedure | acc. 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 5 |
| Applied Standards | EN ISO 13485:2016, Certificate No. Q5 061585 0030 |
| EC Certificates | No. G1 061585 0032; valid until 17.05.2024 |
| Notified Body | TÜV SÜD Product Service GmbH, Ridlerstrasse 65, 80339 München, Germany |
| Identification no. | 0123 |

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 excluding (4).

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

Effective

DECLARATION OF CONFORMITY
Attachment for Medical Devices Class IIa

| Art. No. | Product Name | Remarks |
|----------|---|---------|
| FB 99849 | Uro-Tainer® NaCl 0.9% (10 x 50 ml) | |
| FB 99881 | Uro-Tainer® NaCl 0.9% (60 x 50 ml) | |
| FB 99833 | Uro-Tainer® NaCl 0.9% (10 x 100 ml) | |
| FB 99882 | Uro-Tainer® NaCl 0.9% (60 x 100 ml) | |
| FB 99854 | Uro-Tainer® M NaCl 0.9% (10 x 50 ml) | |
| FB 99853 | Uro-Tainer® M NaCl 0.9% (10 x 100 ml) | |
| FB 99851 | Uro-Tainer® Suby G (10 x 50 ml) | |
| FB 99839 | Uro-Tainer® Suby G (10 x 100 ml) | |
| FB 99867 | Uro-Tainer® Suby G (60 x 100 ml) | |
| 9746609 | Uro-Tainer® Twin Suby G (10 x 60 ml) | |
| FB 99843 | Uro-Tainer® Solutio R (10 x 50 ml) | |
| FB 99841 | Uro-Tainer® Solutio R (10 x 100 ml) | |
| FB 99893 | Uro-Tainer® Solutio R (60 x 50 ml) | |
| FB 99894 | Uro-Tainer® Solutio R (60 x 100 ml) | |
| 9746625 | Uro-Tainer® Twin Solutio R (10 x 60 ml) | |