

B. Braun Medical AG
Seesatz 17
6204 Sempach
Switzerland

DECLARATION OF CONFORMITY

Product Category: Pre-injection cleansing swab

Brand Name	Dosage form	Date of CE marking	Batch No.	Size	Art. No.
Softa® Swabs	Wipes	13.04.2011	LOT 00001 / 1103712Y	100 Wipes	19579

Conformity Assessment Procedure: according to ANNEX VII of the COUNCIL DIRECTIVE 93/42/EEC

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

Class/Rule: Class I (non sterile) / Rule 1

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

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

We herewith declare under our sole responsibility that the above mentioned product meets 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 it, as stated in ANNEX VII.

Sempach, 24.09.2018

B. Braun Medical AG


Peter Egli
Head of Quality Unit CoE Infection Control


Dr. Michael Gluschke
Director Global Regulatory Affairs OPM