

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 061585 0030,  
valid until 31.07.2022

**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, 05.08.2019

B. Braun Medical AG

  
Peter Egli  
Head of Quality Unit CoE Infection Control

  
Dr. Michael Gluschke  
Director Global Regulatory Affairs OPM