

B. Braun Medical AG
Seesatz 17
6204 Sempach
Switzerland

DECLARATION OF CONFORMITY
FOR MEDICAL DEVICES

Product Category: Pre-injection cleansing swab

Product (Name, Type)	CE marking	Batch	Size	Reference
Softa® Swabs	13.04.2011	LOT 00001 1103712Y	100 Pads	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 13485:2003/AC 2007, Certificate No. Q1N 10 06 61585 006

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, 28.04.2011

B. Braun Medical AG


Sandro Di Labio
Head of Quality Management


Dr. Michael Gluschke
Head of Regulatory Affairs