B|BRAUN

Declaration

The certification body of TÜV Management Service GmbH and the TÜV Product Service GmbH confirm that we,

AESCULAP AG
AM AESCULAP-PLATZ
78532 TUTTLINGEN / GERMANY

have established and are maintaining a quality management system according to

ISO 9001:2008
(Certificate Registration No.: 12 100 21724 TMS)
EN ISO 13485:2012 / AC:2012
(Certificate No.: Q1N 14 05 10066 365)

for the following area

Development, Production and Distribution of Implants, Instruments, Containers, Devices, Suture Material, Tissue Adhesives and Procedure Kits.

Furthermore we have implemented the conformity assessment procedure as per annex II, clause 3 of the Medical Device Directive 93/42/EEC of June 14th, 1993 for medical products. (EC certificate No.: G1 14 05 10066 366).

By labeling the products

Aesculap Product Groups
as per attached list

with the CE mark

we, **AESCULAP AG** confirm,
that we follow the essential requirements
according to MDD 93/42/EEC Annex I.

TUTTLINGEN, 2017-02-07

AESCULAP AG,

i. V.

Dr. Stefan Willemsen
Regulatory Affairs

i. A.

S. Maier

Sandra Maier
Regulatory Affairs

B|BRAUN

Attachment to Declaration of 07.02.2017

Aesculap Product Groups
Surgical, diagnostic and dental instruments
Joint implants (hip, knee)
Surgical implants
Implants for osteosynthesis
Neurosurgical vascular implants
Products for ligature
Motor Systems
Sterilization containers and accessories
High frequency surgery devices
Endoscopic systems
Navigation systems
Special suture-sets
Implants for replacement of connective tissue
Tissue adhesives
Vascular prostheses and accessories
Local haemostatics
Other surgical accessories