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, 2015-04-29

AESCULAP AG

i. V.

Rainer Siglinger
Team Leader Ortho-Implants
Regulatory Affairs

AESCULAP AG AESCULAP® Tuttlingen

i. A.

Irene Simon
Regulatory Affairs

Digitally signed by Botnaru Tatiana
Date: 2020.03.22 12:46:08 EET
Reason: MoldSign Signature
Location: Moldova