B|BRAUN

Declaration

The certification body of TÜV Süd Management Service GmbH and the TÜV Süd 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 9001:2015
(Certificate Registration No.: 12 100 21724 TMS)
EN ISO 13485:2016
(Certificate No.: Q5 010066 0435 Rev. 00)

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 VII or per annex II, clause 3 of the Medical Device Directive 93/42/EEC of June 14th, 1993 for medical products (TÜV EC-Certificate No.: G1 010066 0426 Rev. 00 or MEDCERT EC-Certificate No.: 7400GB410200310).

By labeling the products
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, 2021-04-21

AESCULAP AG

i. V.

Dr. Jennifer Grünow
Global Regulatory Affairs

i. A.

Dr. Sebastian Niklaus
Global Regulatory Affairs

B|BRAUN

Attachment to Declaration of 2021-04-21

Article No.	Description	Risk class acc. to MDD 93/42
BA810SU	CARBON STEEL SAFETY SCALPEL #10	IIa
BA811SU	CARBON STEEL SAFETY SCALPEL #11	IIa
BA821SU	CARBON STEEL SAFETY SCALPEL #21	IIa
BA822SU	CARBON STEEL SAFETY SCALPEL #22	IIa
BA824SU	CARBON STEEL SAFETY SCALPEL #24	IIa
BA836SU	CARBON STEEL SAFETY SCALPEL #36	IIa