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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. 01)

for the following area

Design and Development, Production, Technical Service and Distribution of Implants, Instruments, Instrument Management Systems, Containers, Devices, Tissue Adhesives.

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 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, 2023-06-28

AESCULAP AG

i. V.

Rainer Siglinger
Global Regulatory Affairs

i. A.

Benjamin Oswald
Global Regulatory Affairs

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Attachment to Declaration of 2023-06-28

Article No.	Description	Risk class acc. to MDD 93/42
PL561T	LIGATURE CLIP LARGE 20 MAG.=120 PCS.	III
PL565T	LIGATURE CLIP SMALL 30 MAG.=180 PCS.	III
PL567T	LIGATURE CLIP MEDIUM 30 MAG.=180 PCS.	III
PL568T	LIGATURE CLIP MED.LARGE 20 MAG.=120 PCS.	III