

Declaration

For the products as specified below we,

AESFULAP AG
AM AESFULAP-PLATZ
78532 TUTTLINGEN / GERMANY
(SRN: DE-MF-000005504)

have carried out a conformity assessment procedure according to the Medical Device Regulation (EU) 2017/745 by involving the Notified Body as indicated on the CE mark and in relation to the Notified Body as applicable for the respective EU risk class.

Involved Notified Body

CE	Conformity assessment without Notified Body involvement
CE 0123	TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 München, Germany
CE 0482	MEDCERT GmbH, Pilatuspool 2, 20355 Hamburg, Germany

Risk class	Sub-cat.	Procedure	Applicable System Certificate (TÜV SÜD or MEDCERT)
I	--	Annex II & III	n/a
I	s, m, r	Annex IX	Certificate No.: G11 010066 0437 (Rev. xx) or 7400GB448xxxxxx
IIa	--	Annex IX	Certificate No.: G10 010066 0438 (Rev. xx) or 7400GB448xxxxxx
IIb	--	Annex IX	Certificate No.: G10 010066 0438 (Rev. xx) or 7400GB448xxxxxx
IIb	impl.	Annex IX	Certificate No.: G12 010066 0441 (Rev. xx) or 7400GB448xxxxxx
III	--	Annex IX	Certificate No.: G12 010066 0441 (Rev. xx) or 7400GB448xxxxxx + applicable EU Technical Documentation Assessment Certificate

The validity of this document corresponds to the expiry date of the currently applicable system certificate for the respective product.

By labeling the products with the CE mark (see attached list below)

we, **AESFULAP AG**, under sole responsibility confirm,
 that we follow the general safety and performance requirements
 according to MDR (EU) 2017/745, Annex I.

TUTTLINGEN, 2023-03-16

AESFULAP AG

i. V.

Dr. Stefan Willemsen
 Global Regulatory Affairs

i. A.

Dr. Sebastian Niklaus
 Global Regulatory Affairs

Attachment to Declaration of 2023-03-16

Article No.	Description	Basic UDI-DI	Risk class acc. to MDR 2017/745
BC304R	SURGICAL SCISSORS DEL STR S/B 145MM	4039239000000062023	I
BC345R	SURGICAL SCISSORS STR S/S 150MM	4039239000000062023	I
BC374R	DEAVER SCISSORS STR S/B 145MM	4039239000000062023	I
BD029R	TISSUE FORCEPS SERR 160MM	40392390000005392K	I
BD549R	TISSUE FORCEPS 1X2160MM	40392390000005392K	I
BH110R	HALSTED-MOSQUITO FORCEPS DELSTR125MM	403923900000004722C	I
BH111R	HALSTED-MOSQUITO FORCEPS DEL CVD125MM	403923900000004722C	I
BH120R	HALSTED-MOSQUITO FCPSDELSTR1X2125MM	403923900000004722C	I
BJ009R	BABY OVERHOLT DISS.A.LIGAT.FORCEPS 135MM	403923900000004722C	I
BM242R	MAYO-HEGAR NEEDLE HOLDER 190MM	4039239000000038128	I