

Konformitätserklärung *Declaration of Conformity*

Wir / We,

Aesculap AG
Am Aesculap-Platz
78532 Tuttlingen
GERMANY

SRN: DE-MF-000005504

erklären in alleiniger Verantwortung, dass die folgenden Artikel mit den Anforderungen der **Medizinprodukte-Verordnung (EU) 2017/745** übereinstimmen.
*declare under our sole responsibility that the following products are in conformity with the requirements of the **Medical Device Regulation (EU) 2017/745.***

Siehe angehängte Artikelliste / *See attached product list*

Die **Risikoklasse** nach Anhang VIII ist **angehängter Liste** zu entnehmen.
Für die genannten Artikel wurde ein **Konformitätsbewertungsverfahren** nach **Anhang IX, Kapitel I und III** durchgeführt.

*The **risk class** according to Annex VIII is mentioned in **attached list.***
*For the attached products a **conformity assessment procedure** has been carried out according to **Annex IX, Chapter I and III.***

Benannte Stelle / Notified Body: TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 München, Germany, Kennnummer / Identification number: 0123

MDR EU QM System Certificate, 2017/745 on Medical Device, Annex IX Chapter I and III (Class IIa and IIb Devices), No. G10 010066 0438

Gültig bis / *Valid until:*
04.11.2027

Tuttlingen, Germany

i.V.

i.V.

Martin Schäuble
Vice President R&D

Matthias Welke
Director Global Regulatory Affairs

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Zweckbestimmung <i>Intended Use</i>	Scissors are used to cut or prepare e.g. tissue, organs and other medical aids. The umbilical cord scissors are used to cut the umbilical cord during the birth of a child. The bandage scissors is used to cut e.g. dressings.
Basic-UDI-DI:	403923900000059935

Artikelnummer <i>Ref. Number</i>	Bezeichnung <i>Description</i>	Risikoklasse <i>Risk Class</i>
BC110SU	SUSI DELICATE SCISSORS STR.SP/SP 110MM	IIa
BC324SU	SUSI SURG.SCISSORS SP/BP STR.145MM	IIa
BC606SU	SUSI METZENBAUM SCISSORS CVD.180MM	IIa
BC790SU	SUSI UMBILICAL CORD SCISSORS BLUE 160MM	IIa
BC791SU	SUSI UMBILICAL CORD SCISSORS ROSE 160MM	IIa
BC861SU	SUSI BANDAGE SCISSORS 145MM	IIa

Zweckbestimmung <i>Intended Use</i>	The dissecting and tissue forceps are used to hold and grasp e.g. tissue, organs, medical supplies and materials. The sponge forceps are used e.g. to hold and grasp swabs, drainage tubes, medical supplies and materials. The artery and mosquito forceps are used e.g. to grasp, hold and clamp blood vessels, tissue or organs.
Basic-UDI-DI:	4039239000000600ZS

Artikelnummer <i>Ref. Number</i>	Bezeichnung <i>Description</i>	Risikoklasse <i>Risk Class</i>
BD047SU	SUSI DISSECT.FORCEPS W/O TEETH.145MM	IIa
BD222SU	SUSI ADSON DISSECT.FORCEPS W/O T.120MM	IIa
BD239SU	SUSI CUSHING DISSECTING FORCEPS 200MM	IIa
BD512SU	SUSI ADSON TISSUE FCPS FINE 1X2T.120MM	IIa
BD557SU	SUSI TISSUE FORCEPS STD.PATT.1X2T.145MM	IIa
BD671SU	SUSI WAUGH TISSUE FORCEPS1X2TEETH200MM	IIa
BF046SU	SUSI SPONGE FORCEPS W/RATCH.STR.200MM	IIa
BF047SU	SUSI SPONGE FORCEPS W/RCHT CVD.200MM	IIa

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BF059SU	SUSI MAIER SPONGE FCPS W/RTCH.CVD 265MM	IIa
BH110SU	SUSI HALSTED MOSQUITO FORCEPS STR.125MM	IIa
BH111SU	SUSI HALSTED MOSQUITO FORCEPS CVD.125MM	IIa
BH196SU	SUSI BIRKETT ARTERY FORCEPSSTR.185MM	IIa
BH197SU	SUSI BIRKETT ARTERY FORCEPSCVD.185MM	IIa
BH424SU	SUSI PEAN ARTERY FORCEPS STR.145MM	IIa

Zweckbestimmung <i>Intended Use</i>	The needle holders are used to hold, grasp and guide surgical needles during suturing.
Basic-UDI-DI:	4039239000000601ZU

Artikelnummer <i>Ref. Number</i>	Bezeichnung <i>Description</i>	Risikoklasse <i>Risk Class</i>
BM226SU	SUSI CRILE-WOOD NEEDLE HOLDER 200MM	IIa
BM235SU	SUSI MAYO-HEGAR NEEDLEHOLDER 150MM	IIa

Zweckbestimmung <i>Intended Use</i>	The SUSI WEITLANER wound retractor is used to spread wound edges. The SUSI ROUX retractor is used to hold and keep away tissue and/or organs.
Basic-UDI-DI:	4039239000000602ZW

Artikelnummer <i>Ref. Number</i>	Bezeichnung <i>Description</i>	Risikoklasse <i>Risk Class</i>
BT028SU	SUSI ROUX RETRACTOR 170MM	IIa
BV067SU	SUSI WEITLANER RETRACTOR 3X4T.SEMI-SHARP	IIa

Zweckbestimmung <i>Intended Use</i>	The sharp spoon is used for scraping off defective tissue and/or impurities.
Basic-UDI-DI:	403923900000060323

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Artikelnummer <i>Ref. Number</i>	Bezeichnung <i>Description</i>	Risikoklasse <i>Risk Class</i>
FK850SU	SUSI CURETTE SHARP DBEND.180MM	IIa

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