

Konformitätserklärung *Declaration of Conformity*

Effective

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

EU Quality Management System Certificate (MDR) – Pursuant to Regulation (EU) 2017/745 on Medical
Devices, Annex IX Chapters I and III; No. G10 010066 0438

Gültig bis / *Valid until*:
23.07.2030

Tuttlingen, Germany

i.V.

Martin Schaeuble
Vice President R&D

i.V.

Matthias Welke
Director Global Regulatory Affairs

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Zweckbestimmung <i>Intended Purpose</i>	The scissors are used to cut or prepare tissues, organs and medical aids. The umbilical cord scissors are used to cut the umbilical cord after the birth of a child. The bandage scissors is used to cut medical aids (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	Ila
BC324SU	SUSI SURG.SCISSORS SP/BP STR.145MM	Ila
BC606SU	SUSI METZENBAUM SCISSORS CVD.180MM	Ila
BC790SU	SUSI UMBILICAL CORD SCISSORS BLUE 160MM	Ila
BC791SU	SUSI UMBILICAL CORD SCISSORS ROSE 160MM	Ila
BC861SU	SUSI BANDAGE SCISSORS 145MM	Ila

Zweckbestimmung <i>Intended Purpose</i>	The dissecting and tissue forceps are used to hold and grasp tissues, organs, medical supplies and materials. The sponge forceps are used to hold and grasp swabs, drainage tubes, medical supplies and materials. The artery and mosquito forceps are used to grasp, hold and clamp blood vessels, tissues 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	Ila
BD222SU	SUSI ADSON DISSECT.FORCEPS W/O T.120MM	Ila
BD239SU	SUSI CUSHING DISSECTING FORCEPS 200MM	Ila
BD512SU	SUSI ADSON TISSUE FCPS FINE 1X2T.120MM	Ila
BD557SU	SUSI TISSUE FORCEPS STD.PATT.1X2T.145MM	Ila
BD671SU	SUSI WAUGH TISSUE FORCEPS1X2TEETH200MM	Ila
BF046SU	SUSI SPONGE FORCEPS W/RATCH.STR.200MM	Ila
BF047SU	SUSI SPONGE FORCEPS W/RCHT CVD.200MM	Ila
BF059SU	SUSI MAIER SPONGE FCPS W/RTCH.CVD 265MM	Ila
BH110SU	SUSI HALSTED MOSQUITO FORCEPS STR.125MM	Ila
BH111SU	SUSI HALSTED MOSQUITO FORCEPS CVD.125MM	Ila
BH196SU	SUSI BIRKETT ARTERY FORCEPSSTR.185MM	Ila
BH197SU	SUSI BIRKETT ARTERY FORCEPSCVD.185MM	Ila
BH424SU	SUSI PEAN ARTERY FORCEPS STR.145MM	Ila

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Zweckbestimmung <i>Intended Purpose</i>	The needle holders are used to hold, grasp and guide surgical suture needles and suture materials.
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	Ila
BM235SU	SUSI MAYO-HEGAR NEEDLEHOLDER 150MM	Ila

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

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

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

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

Konformitätshistorie / Conformity History

Version <i>Version</i>	Änderungsbeschreibung <i>Change Description</i>
1.0	Initial (MDR)
2.0	New template (ver.13) for sampling submission
3.0	New template (ver.14) including intended purpose/ TDU project: validity period extended by 5 years

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Title: Declaration of Conformity_Single use Surgical Instruments - class IIa Initiator: Yumemi ? Brunschoen

This document is signed electronically in compliance with the B. Braun electronic signature policies and procedures by following persons:

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