Effective

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

EU Quality Management System Certificate (MDR) – Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III; No. G11 010066 0437

Gültig bis / *Valid until*:
12.01.2028

Tuttlingen, Germany

i.V.

Martin Schäuble
Vice President R&D

i.V.

Matthias Welke
Director Global Regulatory Affairs

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Zweckbestimmung *Intended Purpose*	The retraction system Münster is used in stomach and vascular surgery as well as gynecology.
Basic-UDI-DI:	**40392390000004482F**

Artikelnummer *Ref. Number*	**Bezeichnung** *Description*	**Risikoklasse** *Risk Class*
BV825R	MUNSTER BLADE ROD 150MM	I
BV826R	MUNSTER ROD EXTENSION100MM	I
BV827R	MUNSTER ROD END-PART60MM	I
BV828R	EXTENSION ROD F/BT708R 200MM SMOOTH	I
BV833R	MUENSTER OCTAG.NOTCH ROD 200MM W/JOINT	I
BV834R	MUNSTER ANGLED ROUND NOTCH ROD 200MM	I
BV835R	ADAPTER FOR BALL SNAP CLOSURE VALVES	I
BV839R	MUNSTER OCTANGULAR NOTCH ROD100MM	I
BV840R	MUENSTER OCTANGULAR NOTCH ROD 220MM	I

Zweckbestimmung *Intended Purpose*	The Frankfurt retraction system is used to extend the operative access in goiter and abdominal pediatric surgery, in combination with the instruments intended for this purpose.
Basic-UDI-DI:	**4039239000001232ZS**

Artikelnummer *Ref. Number*	**Bezeichnung** *Description*	**Risikoklasse** *Risk Class*
BW085R	WOUND RETRACTOR 14X18MM FRANKFURT MODEL	I
BW086R	WOUND RETRACTOR 17X16MM FRANKFURT MODEL	I
BW087R	WOUND RETRACTOR 18X22MM FRANKFURT MODEL	I
BW088R	WOUND RETRACTOR 30X19MM FRANKFURT MODEL	I
BW090R	WOUND RETRACTOR 30X20MM FRANKFURT MODEL	I
BW091R	WOUND RETRACTOR 30X40MM FRANKFURT MODEL	I
BW092R	WOUND RETRACTOR 35X11MM FRANKFURT MODEL	I
BW093R	WOUND RETRACTOR 55X20MM FRANKFURT MODEL	I
BW094R	WOUND RETRACTOR 51X30MM FRANKFURT MODEL	I

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Zweckbestimmung *Intended Purpose*	Surgical retractors are used to separate the edges of a surgical incision, or a body orifice, or to hold back organs and tissues to keep open the operation site.
Basic-UDI-DI:	**4039239000001233ZU**

Artikelnummer *Ref. Number*	**Bezeichnung** *Description*	**Risikoklasse** *Risk Class*
BV327R	RETRACTOR ONLY BSC.SPREAD RANGE 90MM	I
BV582R	PARKS CENTER BLADE F/BV581R	I
BV583R	P.RECTAL BLADESF/BV581R 70MM	I
BV584R	P.SPHINCTER BLDSF/BV581R93X22MM	I
BV586R	PARKS BLADES F/BV581R 90X22MM	I
BV589R	PARKS BLADES F/BV581R 150X23MM	I
FB805R	FINOCHIETTO-BURFORD RIB SPREADRCOMPLETE	I
FB806R	FINOCHIETTO BLDS F/FB805R45X64MM	I
FB807R	FINOCHIETTO BLDS F/FB805R75X64MM	I
FB808R	DE'BAKEY STERNUM AND RIB SPREADER	I
FB809R	DE'BAKEY RIB SPREADER F/FB808	I
FB810R	PAIR OF BLADES F/FB808 30X30MM	I
FB811R	PAIR OF BLADES F/FB808 40X40MM	I
FB812R	PAIR OF BLADES F/FB808 50X50MM	I
FB813R	STERNOTOMY BLADES 50X66MM	I
FB814R	DE'BAKEY RIB SPREADER COMPLETE200X225MM	I
FB815R	DE'BAKEY RIB SPREADER ONLY 285X225MM	I
FB816R	DE'BAKEY BLADES 60X60MM	I
FB817R	DE'BAKEY BLADES 50X80MM	I
FB818R	DE'BAKEY BLADES 40X100MM	I
FB819R	DE'BAKEY BLADES 80X60MM	I
FB820R	MERCEDES THORAX SPREADER CPL.	I
FB821R	SPREADER ONLY F.FB820R	I
FB822R	PAIR OF BLADES SMALL 48X69MM	I
FB823R	PAIR OF BLADES LARGE 72X78MM	I
FB835R	HAIGHT RIB SPREADER 30X30MM-BLDS	I
FB836R	RIB SPREADER 28X32MM-BLDS	I
FB840R	SELLOR RIB SPREADER SWIVEL BLD 200MM	I
FB841R	BAILEY RIB SPREADER/CONTRACTORPED200MM	I
FB842R	BAILEY RIB SPRDR/CONTRACTORADULT200MM	I
FB844R	BAILEY RIB SPREADER/CONTRACTOR 150MM	I
FB845R	MORSE STERNOTOMY RETRACTOR PED 15X22MM	I

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Artikelnummer ***Ref. Number***	**Bezeichnung** ***Description***	**Risikoklasse** ***Risk Class***
FB846R	MORSE STERNOTOMY RETRACTOR ADULT 23X29MM	I
FB852R	STRUCK INFANT RIB SPREADER COMPLETE	I
FB853R	STRUCK INFANT RIB SPREADER ONLY	I
FB854R	STRUCK BLADES F/FB853R 10X10MM	I
FB855R	STRUCK BLADES F/FB853R 10X15MM	I
FB856R	STRUCK BLADES F/FB853R 10X20MM	I
FB857R	STRUCK BLADES F/FB853R 15X20MM	I
FB858R	STRUCK BLADES F/FB853R 20X20MM	I
FC040A	RIP SPREADER BABY FINOCHIETTO ALUMINIUM	I
FC041A	RIB SPREADER FINOCHIETTO-HAIGHT ALUMI.	I
FC042A	FINOCHIETTO RIB SPRDR ALUM 31X45 BLDS	I
FC043A	RIP SPREAD.FINOCHIETTO MED.SIZED ALUM	I
FC044A	RIP SPREADER FINOCHIETTO LARGE ALUMI.	I
FC060R	AMI STERNUM RETRACTOR COMPLET	I
FC061R	AMI STERNUM RETRACTOR ALONE	I
FC062R	SET OF BLADES F.FC061R	I
FC063R	VALVE 30X100MM F.FC061R	I
FC064R	VALVE 40X100MM F.FC061R	I

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Konformitätshistorie / Conformity History

Version ***Version***	**Änderungsbeschreibung** ***Change Description***
1.0	Initial (MDR)
2.0	New template (ver.14) including intended purpose/ version history ECM 191053 (SAP text change)

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Title: Declaration of Conformity_Retraction Systems_class Ir TÜV Initiator: Yumemi ? Brunschoen

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

UserName: Brunschoen, Yumemi (shidyude)
Title: Regulatory Affairs
Date: Wednesday, 18 June 2025, 13:49 W. Europe Daylight Time
Meaning: Document signed as Author
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UserName: Welke, Matthias (welkmade)
Title: Director Regulatory Affairs
Date: Wednesday, 18 June 2025, 15:18 W. Europe Daylight Time
Meaning: Approve Document
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UserName: Schaeuble, Martin (schamnde)
Title: Vice President R&D Surgical Instruments
Date: Thursday, 19 June 2025, 10:01 W. Europe Daylight Time
Meaning: Approve Document
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