

Konformitätserklärung *Declaration of Conformity*

Wir / We,

Aesculap AG
Am Aesculap-Platz
78532 Tuttlingen
GERMANY

SRN: _____

(wird ergänzt, sobald verfügbar / will be added as soon as available)

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**.*

Artikel siehe angehängte Liste / *products see attached list*

Die **Risikoklasse** nach Anhang VIII ist **angehängter Liste** zu entnehmen.
Für die genannten Artikel wurde ein **Konformitätsbewertungsverfahren** nach **Anhang IX** 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**.*

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

Die **Gültigkeit** der Konformitätserklärung entspricht der Geltungsdauer des aktuell gültigen EG Zertifikates -
vollständiges QM-System nach Anhang IX, (EU) 2017/745.

Validity of the Declaration of Conformity corresponds to the currently valid EC certificate - Full QA System,
Annex IX, (EU) 2017/745.

Tuttlingen, 2020-09-03

i.V.

Martin Schäuble
Vice President R&D
R&D Abdominal & Cardio-Thoracic Surgery &
Product Maintenance

i.V.

Juliana Vaz Nürnberger
Director Global Regulatory Affairs

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Konformitätserklärung *Declaration of Conformity*

Zweckbestimmung Intended Use	The instruments are used in the general surgical use of all medical disciplines. Bone rongeurs are used to remove bone and bone-like structures.
Basic-UDI-DI:	403923900000169233

Artikelnummer Ref. Number	Bezeichnung Description	Risikoklasse Risk Class
DX500R	ERGOPLANT B.RONGEUR LUER-FRIEDMANN 145MM	I
FG052R	SYPERT BONE RONGEUR 8/360MM	I
FO399R	STELLBRINK SYNOVECTOMY RONGSLT-CVD175MM	I
FO400R	STELLBRINK SYNOVECTOMY RONGEURCVD170MM	I
FO406R	FRIEDMAN MCRO RNGRSSTR1.3MMX19MM 140MM	I
FO407R	MICRO RONGEURCVD1.3MMX20MM BITE 140MM	I
FO409R	LUER-FRIEDMANN BONE RONGEUR CVD 145MM	I
FO410R	BONE RONGEUR CVD 140MM	I
FO411R	LUER BONE RONGEUR ANG 150MM	I
FO412R	LUER BONE RONGEUR CVD155MM	I
FO413R	BONE RONGEUR CVD.45°	I
FO415R	BLUMENTHAL BONE RONGEUR CVD 155MM	I
FO416R	BLUMENTHAL BONE RONGEUR 155MM	I
FO428R	HAKANSSON BONE RONGEUR170MM	I
FO430R	JANSEN BONE RONGEUR STR 175MM	I
FO432R	JANSEN BONE RONGEUR CVD 175MM	I
FO440R	ALEXANDER BONE RONGEUR140MM	I
FO442R	JANSEN BONE RONGEUR ANG190MM	I
FO450R	LEMPERT BONE RONGEUR STR200MM	I
FO451R	LEMPERT BONE RONGEUR CVD 200MM	I
FO453R	BEYER BONE RONGEUR CVD 180MM	I
FO455R	MEAD BONE RONGEUR CVD SQ-TIP 165MM	I
FO457R	BANE-HARTMAN BONE RONGEUR CVD 175MM	I
FO460R	LUER BONE RONGEUR STR 175MM	I
FO461R	LUER BONE RONGEUR CVD 175MM	I
FO462R	LUER BONE RONGEUR STR OVAL-CUP180MM	I
FO463R	LUER BONE RONGEUR CVD OVAL-CUP180MM	I
FO467R	TROTTER BONE RONGEUR LAT-CVD205MM	I

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FO470R	OLIVECRONA BONE RONGEUR CVD 205MM	
FO472R	GULEKE BONE RONGEUR CVD205MM	
FO474R	BONE RONGEUR NORTHFIELD	
FO475R	PENNYBACKER RONGEUR 205MM	
FO500R	BO.BONE RONGEUR NARRDBACT3MM 155MM	
FO502R	B BONE RONGEUR WIDE DBACT5MM 160MM	
FO511R	MAYFIELD BONE RONGEUR CVD175MM	
FO514R	BEYER BONE RONGEUR CVD DBL-ACT180MM	
FO515NR	BONE RONGEUR MEDIUM STRONG CVD 180MM	
FO515R	ZAUFAL-JANSEN BONE RONGEUR CVD180MM	
FO516NR	BONE RONGEUR DELICATE CVD 240MM	
FO517NR	BONE RONGEUR MEDIUM STRONG CVD 240MM	
FO518NR	BONE RONGEUR STRONG CVD 180MM	
FO518R	RUSKIN BONE RONGEUR CVD 190MM	
FO520NR	BONE RONGEUR DELICATE CVD 180MM	
FO520R	MARQUARDT BONE RONGEUR CVD 200MM	
FO521NR	BONE RONGEUR STRONG CVD 240MM	
FO521R	ROETTGEN-RUSKIN BONE RONGEUR 240MM	
FO522R	ECHLIN BONE RONGEURJAW 2X10MM 230MM	
FO523R	ECHLIN BONE RONGEUR JAW 3X10MM 230MM	
FO525R	FRYKHOLM BONE RONGEUR 240MM	
FO526R	LEKSELL RONG FCPSDBACT CVD 5X16MM 245MM	
FO527R	LEKSELL RONG FCPSDBACT.CVD 245MM	
FO530NR	BONE RONGEUR VERY STRONG LAT-ANG 240MM	
FO530R	STILLE BONE RONGEUR230MM	
FO532NR	BONE RONGEUR VERY STRONG STR 240MM	
FO532R	LEKSELL-STILLE BONE RONGEUR 240MM	
FO534NR	BONE RONGEUR VERY STRONG CVD 240MM	
FO534R	STILLE-RUSKIN BONE RONGEUR240MM	
FO550NR	BONE RONGEUR EXTRA STRONG STR 240MM	
FO550R	LUER-STILLE BONE RONGEUR STR 225.MM	
FO551NR	BONE RONGEUR EXTRA STRONG CVD 240MM	
FO551R	LUER-STILLE BONE RONGEUR CVD 225MM	
FO555R	SEMB BONE RONGEUR 240MM	
FO566R	LUER-STILLE BONE RONGEUR CVD270MM	
FO570R	SAUERBRUCH-CORYLLOS RNGEURRDCUP310MM	
FO572R	SAUERBRUCH-CORYLLOS RNGEURSQCUP310MM	
FO599R	SYNOVECTOMY RONGEUR CVD 130MM	
MD615	ADSON CRANIAL RONGEUR STR.200MM	
MD617	LEMPERT BONE RONGEUR STR 2MM 165MM	
OK400R	JANSEN-MIDDLETON SEPTUM FORCEPS200MM	
OK405R	JANSEN-MIDDLETON SEPTUM FORCEPS 200MM	
OK410R	CRAIG SEPTUM FCPSSTR SPOON-SHP165MM	
OK412R	CRAIG-DOMNICK SEPTUM FCPSLFT-CVD165MM	
OK422R	HEYMANN-KNIGHT SEPTUM FORCEPS190MM	
OK433R	LUC SEPTUM FEN FORCEPS SM 200MM	
OK434R	LUC SEPTUM FEN FORCEPS LRG200MM	
OK435R	NASAL FORCEPS LUC 6.0MM	

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OK436R	LUC SEPTUM FEN FORCEPS 195MM 7.5MM	I
OK440R	BRUENINGS SEPTUM FORCEPS FEN SM190MM	I
OK441R	BRUENINGS SEPTUM FORCEPS FENMED190MM	I
OK442R	BRUENINGS SEPTUM FORCEPS FENLG190MM	I
OK443R	BRUENINGS SEPTUM FCPS FENX-LRG190MM	I

Zweckbestimmung Intended Use	The instruments are used in the general surgical use of all medical disciplines. Bone cutting forceps are used to cut bone or bone-like structures.
Basic-UDI-DI:	403923900000169335

Artikelnummer Ref. Number	Bezeichnung Description	Risikoklasse Risk Class
DX501R	ERGOPLANT BONE CUTTING FORCEPS 150MM	I
FO601R	BONE-CUTTING FORCEPS ANG130MM	I
FO602R	BONE-CUTTING FORCEPS CVD 170MM	I
FO604R	STAMM BONE-CUTTING FORCEPS 150MM	I
FO610R	BOEHLER BONE-CUTTING FORCEPSSTR145MM	I
FO611R	BOEHLER BONE-CUTTING FORCEPSANG145MM	I
FO612R	BONE-CUTTING FORCEPS FINE170MM	I
FO614R	MC'INDOE BONE-CUTTING FORCEPSANG175MM	I
FO620R	LISTON BONE-CUTTING FORCEPS STR140MM	I
FO622R	LISTON BONE-CUTTING FORCEPS STR170MM	I
FO624R	LISTON BONE-CUTTING FORCEPS STR 200MM	I
FO626R	LISTON BONE-CUTTING FORCEPS STR 220MM	I
FO632R	LISTON BONE-CUTTING FORCEPS CVD 170MM	I
FO634R	LISTON BONE-CUTTING FORCEPS CVD 200MM	I
FO636R	LISTON BONE-CUTTING FORCEPS CVD 220MM	I
FO640R	RUSKIN BONE-CUTTING FORCEPS STR 190MM	I
FO641NR	BONE CUTTING FORCEPS ANG 180MM	I
FO641R	RUSKIN BONE-CUTTING FORCEPS CVD 190MM	I
FO645NR	BONE CUTTING FORCEPS ANG 240MM	I
FO645R	LISTON BONE-CUTTING FORCEPS CVD 240MM	I
FO646R	LISTON BONE-CUTTING FORCEPS STR280MM	I
FO647R	LISTON BONE-CUTTING FORCEPS CVD 280MM	I
FO648R	LISTON-STILLE BONE-CUTTING FCPS 265MM	I
FO649R	LISTON-KEY-HORSLEY BNE-CUTTING FCP255MM	I
OK378R	KAZANJIAN BONE-CUTTING FORCEPS 185MM	I

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