

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: DNV MEDCERT GmbH, Pilatuspool 2, 20355 Hamburg, Germany
Kennnummer / Identification number: 0482

EU Quality Management System Certificate (MDR) – Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III; No. 7400GB448250428

Gültig bis / *Valid until:*
10.03.2027

Tuttlingen, Germany

i.V.

Markus Siller
Vice President R&D

i.V.

Matthias Welke
Director Global Regulatory Affairs

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Zweckbestimmung <i>Intended Purpose</i>	The instruments are used in surgical procedures for the implantation or removal of spinal implants.
Basic-UDI-DI:	40392390000015622M

Artikelnummer <i>Ref. Number</i>	Bezeichnung <i>Description</i>	Risikoklasse <i>Risk Class</i>
FF913R	CASPAR GRAFT POSITIONING TAMP - 3MM DIA	I
FF914R	CASPAR GRAFT POSITIONING TAMP - 5MM DIA	I
FF915R	CASPAR GRAFT POSITIONING TAMP - 8MM DIA	I
FF917R	CASPAR VERTEBRAL BODY DISSECTOR-FLAT TIP	I
FF918R	CASPAR VERTEBRAL BODY DISSECTOR-BLVD TIP	I
FF927R	CASPAR GRAFT CUTTER 10MMF/GRAFT 9-12MM	I
FF928R	CASPAR GRAFT CUTTER 7MM F/GRAFT 6-9MM	I
FF975R	CASPAR TAP	I
FG413R	CASPAR EVOLUTION TAP	I

Zweckbestimmung <i>Intended Purpose</i>	The instruments are used in surgical procedures for the implantation or removal of spinal implants.
Basic-UDI-DI:	40392390000015582W

Artikelnummer <i>Ref. Number</i>	Bezeichnung <i>Description</i>	Risikoklasse <i>Risk Class</i>
AA845R	CASPAR CALIPER F/BONE GRAFT 150MM	Ila
BV435R	CASPAR RETRACTOR HOOK (SGL.PRONG) 38MM	Ila
BV437R	CASPAR RETRACTOR HOOK (SGL.PRONG) 58MM	Ila
BV441R	CASPAR RETRACTOR BLADE 2 PRONGS 32X22MM	Ila
BV442R	CASPAR RETRACTOR BLADE 2 PRONGS 37X22MM	Ila
BV443R	CASPAR RETRACTOR BLADE 2 PRONGS 42X22MM	Ila
BV444R	CASPAR RETRACTOR BLADE 2 PRONGS 47X22MM	Ila
BV445R	CASPAR RETRACTOR BLADE 2 PRONGS 52X22MM	Ila
BV446R	CASPAR RETRACTOR BLADE 2 PRONGS 57X22MM	Ila
BV447R	CASPAR RETRACTOR BLADE 2 PRONGS 62X22MM	Ila
BV448R	CASPAR RETRACTOR BLADE 2 PRONGS 67X22MM	Ila
BV451R	CASPAR RETRACTOR BLADE 3 PRONGS 32X37MM	Ila
BV452R	CASPAR RETRACTOR BLADE 3 PRONGS 37X37MM	Ila
BV453R	CASPAR RETRACTOR BLADE 3 PRONGS 42X37MM	Ila
BV454R	CASPAR RETRACTOR BLADE 3 PRONGS 47X37MM	Ila
BV455R	CASPAR RETRACTOR BLADE 3 PRONGS 52X37MM	Ila
BV456R	CASPAR RETRACTOR BLADE 3 PRONGS 57X37MM	Ila
BV457R	CASPAR RETRACTOR BLADE 3 PRONGS 62X37MM	Ila
BV458R	CASPAR RETRACTOR BLADE 3 PRONGS 67X37MM	Ila

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BV461R	CASPAR RETRACTOR BLADE 4 PRONGS 32X52MM	Ila
BV462R	CASPAR RETRACTOR BLADE 4 PRONGS 37X52MM	Ila
BV463R	CASPAR RETRACTOR BLADE 4 PRONGS 42X52MM	Ila
BV464R	CASPAR RETRACTOR BLADE 4 PRONGS 47X52MM	Ila
BV465R	CASPAR RETRACTOR BLADE 4 PRONGS 52X52MM	Ila
BV466R	CASPAR RETRACTOR BLADE 4 PRONGS 57X52MM	Ila
BV467R	CASPAR RETRACTOR BLADE 4 PRONGS 62X52MM	Ila
BV468R	CASPAR RETRACTOR BLADE 4 PRONGS 67X52MM	Ila
FF885R	CASPAR EVOLUTION SINGLE DRILL GUIDE	Ila
FF886R	CASPAR EVOL.DOUBLE DRILL GUIDE BICORT.	Ila
FF891R	CASPAR CERVICAL DISTRACTOR-RIGHT	Ila
FF893R	CASPAR X-LONG CERVICAL DISTRACTOR-RIGHT	Ila
FF901R	CASPAR CERVICAL DISTRACTOR-LEFT	Ila
FF903R	CASPAR X-LONG CERVICAL DISTRACTOR-LEFT	Ila
FF906R	CASPAR DISTRACTION PIN SCREWDRIVER	Ila
FF908R	CASPAR DRILL FOR DISTRACTION PINS	Ila
FF911R	CASPAR BONE GRAFT HOLDER AND IMPACTOR	Ila
FF954R	CASPAR PLATE SCREWDRIVER	Ila
FF957R	CASPAR EVOLUTION SCREWDRIVER BALL ENDED	Ila
FF964R	CASPAR SCREW HOLDING SHEATH F/FF954R	Ila
FF965R	CASPAR DEPTH GAUGE 10-50MM	Ila
FF969R	CASPAR PLATE HOLDING FORCEPS 190MM	Ila
FG315R	IMPACTOR FOR FG310R	Ila
FG415R	CASPAR EVOL.DOUBLE DRILL GUIDE MONOCORT.	Ila
FW848R	DISTRACTOR F/LOCKABLE DISTRACT.SCREW RT	Ila
FW849R	DISTRACTOR F/LOCKABLE DISTRACT.SCREW LT	Ila
FW850R	SCREWDRIVER F/LOCKABLE DISTRACTION SCREW	Ila

Zweckbestimmung <i>Intended Purpose</i>	The instruments are used in surgical procedures for the implantation or removal of spinal implants.
Basic-UDI-DI:	4039239000015592Y

Artikelnummer <i>Ref. Number</i>	Bezeichnung <i>Description</i>	Risikoklasse <i>Risk Class</i>
FF897R	CASPAR DRILL GUIDE FOR FF891R & FF893R	Ila
FF907R	DISTRACTION DRILL GUIDE F/FF901&FF903	Ila

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Zweckbestimmung <i>Intended Purpose</i>	The instruments are used in surgical procedures for the implantation or removal of spinal implants.
Basic-UDI-DI:	40392390000023162B

Artikelnummer <i>Ref. Number</i>	Bezeichnung <i>Description</i>	Risikoklasse <i>Risk Class</i>
FF904SB	CASPAR DISTRACTION PIN 14MM	Ila
FF905SB	CASPAR DISTR PIN16MMSTER	Ila
FF909SB	CASPAR DISTR PIN18MMSTER	Ila
FF912SB	CASPAR DISTR PIN12MMSTER	Ila
FW855SU	DISTRACTION SCREW 16MM LOCKABLE	Ila
FW856SU	DISTRACTION SCREW 18MM LOCKABLE	Ila
FW861SU	DISTRACTION SCREW 12MM LOCKABLE	Ila
FW862SU	DISTRACTION SCREW 14MM LOCKABLE	Ila

Zweckbestimmung <i>Intended Purpose</i>	The instrument set contains instruments for surgical procedures at the spine.
Basic-UDI-DI:	40392390000023182F

Artikelnummer <i>Ref. Number</i>	Bezeichnung <i>Description</i>	Risikoklasse <i>Risk Class</i>
BV450R	CASPAR LUMBAR RETRACTOR CPL.	Ila
FF890R	CASPAR CERVICAL DISTRACTION SET-RIGHT	Ila
FF900R	CASPAR CERVICAL DISTRACTION SET-LEFT	Ila

Konformitätshistorie / Conformity History

Version <i>Version</i>	Änderungsbeschreibung <i>Change Description</i>
1.0	Initial version
2.0	Update to new DoC template; Addition of SRN no.; Intended use replaced by Intended Purpose
3.0	Update to new DoC template; BUDI update

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Title: Caspar Instruments_Declaration of Conformity_Class Ir_Ila_MEDCERT Initiator: Fabian ? Thronicke

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

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