

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**.*

Siehe angehängte Artikelliste / See attached productlist

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.*

i.V.

Martin Schäuble
Vice President R&D

i.V.

Dr. Ina Wüstefeld
Vice President Regulatory & Medical Scientific Affairs

Konformitätserklärung *Declaration of Conformity*

Zweckbestimmung <i>Intended Use</i>	The titanium cassette with ligature and marking clips is used for the ligature of vessels and hollow organs and for marking anatomical structures. The product is used in combination with Aesculap clip appliers.
Basic-UDI-DI:	4039239000000324ZR

Artikelnummer <i>Ref. Number</i>	Bezeichnung <i>Description</i>	Risikoklasse <i>Risk Class</i>
PL506R	MULTIFIRE CLIP APPL 10MM 370MM	I
PL508R	MULTIFIRE CLIP APPL 10MM 260MM	I
PL512R	CLIP APPLIC.D:5/310MM F.CLIP PL572T	I
PL600R	CLIP APPLIC.D:5/205MM F.CLIP PL572T	I
PL601R	SHAFT ALONE 205MM F.PL600R	I

Zweckbestimmung <i>Intended Use</i>	The titanium cassette with ligating and marking clips and CO2 cartridge is used for the ligation of vessels and hollow organs and for marking anatomical structures. The product is used in combination with Aesculap clip appliers.
Basic-UDI-DI:	40392390000005752P

Artikelnummer <i>Ref. Number</i>	Bezeichnung <i>Description</i>	Risikoklasse <i>Risk Class</i>
PL603R	MULTIF.CLIP APPL.TI-P 5/205MM F/SM-CLIP	Ila
PL604R	MULTIF.CLIP APPL.TI-P 5/310MM F/SM-CLIP	Ila
PL606R	MULTIF.CLIP APPL.TI-P 10/370MM F/ML-CLIP	Ila
PL608R	MULTIF.CLIP APPL.TI-P 10/260MM F/ML-CLIP	Ila

Zweckbestimmung <i>Intended Use</i>	The titanium cassette with ligating and marking clips and CO2 cartridge is used for the ligation of vessels and hollow organs and for marking anatomical structures. The product is used in combination with Aesculap clip appliers.
Basic-UDI-DI:	40392390000005762R

Artikelnummer <i>Ref. Number</i>	Bezeichnung <i>Description</i>	Risikoklasse <i>Risk Class</i>
PL520R	CHALLENGER TI-P HANDLE	Ila

Title: Declaration of Conformity (Challenger Class Ir, IIa (active)).docx Initiator: Marius ? Bass

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

UserName: Bass, Marius (bassmade)
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Date: Wednesday, 09 December 2020, 14:04 W. Europe Daylight Time
Meaning: Document signed as Author
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UserName: Wuestefeld, Ina (wuesinde)
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Meaning: Approve Document
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Meaning: Approve Document
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