MED CERT®
Certification. Medical Only.

EU Technical Documentation Assessment Certificate

The Notified Body

MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH
Pilatuspool 2 – 20355 Hamburg – Germany

herewith certifies that the company

Aesculap AG
Am Aesculap-Platz
78532 Tuttlingen
Germany

SRN: DE-MF-000005504

has established and maintains a technical documentation for the medical devices listed in the appendix.

The compliance of this technical documentation to the requirements of the **Regulation (EU) 2017/745 on medical devices** was verified by assessment according to:

Annex IX Chapter II

Any applicable limitations of this certification for certain medical devices are included in the appendix. This certificate assumes that MEDCERT has to be informed about any changes of the assessed device. Changes need further approval by MEDCERT.

Effective date:	**2021-10-08**
Expiry date:	**2026-10-07**
Final assessment report No.:	20201IA01F
Procedure No.:	PP – 20201
Certificate No.:	20201GB450211008
Preceding certificate No.:	–
Preceding certificate date:	–
Identification of changes:	–

For conditions or for limitations to the validity refer to the relevant final assessment report. Examinations and tests performed, e. g. reference to relevant common specifications, harmonised standards, test reports and audit report(s) are recorded in the relevant reports. For placing on the market of the medical devices covered by this certificate, an additional EU Quality Management System Certificate according to Annex IX Chapter I of Regulation (EU) 2017/745 is required.

Hamburg, 2021-10-08

MEDCERT Certification Body
(Lorenz Runge)

The certificate is only valid when provided entirely with all of its pages.
To verify the validity of this certificate, contact info@medcert.de.

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-096

MEDCERT Notified Body Identification Number: 0482

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Appendix of EU Technical Documentation Assessment Certificate

Procedure No.: PP – 20201

Certificate No.: 20201GB450211008

Class: III

Basic UDI-DI: 403923900000005772T

Intended purpose: 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.

Model (Device REF#)	**Device name**
PL569T	LIGATING CLIPS M/L 12/BOX
PL572T	LIGATURE CLIP 12 MAG.= 144 PCS.

This appendix is integral part of the above-referenced certificate.
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Appendix of EU Technical Documentation Assessment Certificate

Procedure No.: PP – 20201

Certificate No.: 20201GB450211008

Class: III

Basic UDI-DI: 403923900000006832T

Intended purpose: 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.

Model (Device REF#)	**Device name**
PL574T	CHALLENGER TI-P SM-LIGAT.CLIPS 12 CARTR.
PL579T	CHALLENGER TI-P ML-LIGAT.CLIPS 12 CARTR.

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