

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 Artikel gehören zur **Risikoklasse I** nach Anhang VIII.
Die **Konformität** wird auf Basis der vorliegenden **technischen Dokumentation** nach den Anhängen II und III erklärt.

The products are classified as **risk class I** according to Annex VIII.
The **conformity** is declared based on the present **technical documentation** according to Annexes II and III.

Tuttlingen, 2021-05-03

i.V.

Martin Schäuble	Dr. Ina Wüstefeld
<i>Vice President R&D</i>	<i>Vice President</i>
<i>R&D Abdominal & Cardio-Thoracic Surgery &</i>	<i>Regulatory & Medical Scientific Affairs</i>
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Dr. Ina Wüstefeld
Vice President
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Effective

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Konformitätserklärung *Declaration of Conformity*

Zweckbestimmung <i>Intended Use</i>	The flexible trocar systems are used in endoscopic operations for introducing instruments and endoscopes into the operating field. The flexible trocars may only be used in conjunction with the appropriate silicone flap valves. The flexible thoracoscopy trocars are used without silicone flap valve.
Basic-UDI-DI:	4039239000001320ZQ

Artikelnummer <i>Ref. Number</i>	Bezeichnung <i>Description</i>
EJ651R	RING WITH INSUFFL.STOPCOCK D:5.5MM
EJ650R	RING WITH INSUFFL.STOPCOCK D:10MM

Zweckbestimmung <i>Intended Use</i>	The reusable trocar system is used in operations in laparoscopic general surgery, gynecology and urology. It serves to create and maintain an approach to the operating field for instruments and endoscopes in laparoscopic operations. Endoscopic instruments of 5 mm (5 mm trocar), 5 –10 mm (10 mm trocar) and of 5-12 mm (13 mm trocar) can be inserted. It serves to create and maintain an approach to the operating field for instruments and endoscopes in laparoscopic operations using the HASSON technique. Endoscopic instruments of up to 5 –10 mm (10 mm trocar) diameter can be inserted. They may only be used in conjunction with the corresponding silicone flap valve.
Basic-UDI-DI:	40392390000013192A

Artikelnummer <i>Ref. Number</i>	Bezeichnung <i>Description</i>
EJ640P	REDUCING CAP F/MOD TROCARS10-5MM
EJ641P	REDUCING CAP 12.5-10.5MM

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Zweckbestimmung <i>Intended Use</i>	The trocars are used in endoscopic operations for introducing instruments and endoscopes into the operating field. The trocar bodies/trocar bodies for manual opening may only be used in combination with the trocar sleeves of the MIT Trocar System and with the silicone flap valve.
Basic-UDI-DI:	403923900000131624

Artikelnummer <i>Ref. Number</i>	Bezeichnung <i>Description</i>
EJ581R	TROCAR BODY ALONE D:13MM
EJ700R	TROCAR BODY 5.5MM
EJ710R	TROCAR BODY MANUAL OPENING 5.5MM
EJ750R	TROCAR BODY 10MM
EJ760R	TROCAR BODY MANUAL OPENING W/INSUL.10MM

Zweckbestimmung <i>Intended Use</i>	The reduction sleeves are used during operations in general laparoscopic surgery, gynecology and urology to prevent leaks when inserting smaller diameter instruments into 5- / 10- / 12- /13- / 20 mm trocars and to insert needles or swabs safely through the trocar valve unit, for example.
Basic-UDI-DI:	40392390000013192A

Artikelnummer <i>Ref. Number</i>	Bezeichnung <i>Description</i>
EJ642P	REDUCING CAP 13/10/5.5MM

Zweckbestimmung <i>Intended Use</i>	The reduction sleeves are used during operations in general laparoscopic surgery, gynecology and urology to prevent leaks when inserting smaller diameter instruments into 5- / 10- / 12- /13- / 20 mm trocars and to insert needles or swabs safely through the trocar valve unit, for example.
Basic-UDI-DI:	403923900000131828

Artikelnummer <i>Ref. Number</i>	Bezeichnung <i>Description</i>
EJ624P	SEAL.CAP F.REDUCING SLEEVE 20 TO 10MM

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