

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 II 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 II and III.*

Gültig bis / *Valid until*:
22.05.2029

Tuttlingen, Germany

i.V.

Martin Schäuble
Vice President R&D

i.V.

Matthias Welke
Director Global Regulatory Affairs

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Konformitätserklärung

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Zweckbestimmung <i>Intended Use</i>	Trocars and related accessories are used to create and maintain access to the surgical field for instruments and endoscopes during laparoscopic procedures.
Basic-UDI-DI:	4039239000001320ZQ

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

Zweckbestimmung <i>Intended Use</i>	Trocars and related accessories are used to create and maintain access to the surgical field for instruments and endoscopes during laparoscopic procedures.
Basic-UDI-DI:	40392390000013192A

Artikelnummer <i>Ref. Number</i>	Bezeichnung <i>Description</i>	Risikoklasse <i>Risk Class</i>
EJ640P	REDUCING CAP F/MOD TROCARS10-5MM	I
EJ641P	REDUCING CAP 12.5-10.5MM	I
EJ642P	REDUCING CAP 13/10/5.5MM	I

Zweckbestimmung <i>Intended Use</i>	Trocars and related accessories are used to create and maintain access to the surgical field for instruments and endoscopes during laparoscopic procedures.
Basic-UDI-DI:	403923900000131624

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

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Zweckbestimmung <i>Intended Use</i>	Trocars and related accessories are used to create and maintain access to the surgical field for instruments and endoscopes during laparoscopic procedures.
Basic-UDI-DI:	403923900000131828

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

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Title: Declaration of Conformity trocares and accessories class I.docx Initiator: Anne Katrin ? Wacker

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