

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: TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 München,
Germany, Kennnummer / Identification number: 0123

EU Quality Management System Certificate (MDR)
Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX, Chapters I and III
No. G11 010066 0437

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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Zweckbestimmung <i>Intended Use</i>	Trocars are used to create an access point into the maxillary sinus.
Basic-UDI-DI:	4039239000001312ZR

Artikelnummer <i>Ref. Number</i>	Bezeichnung <i>Description</i>	Risikoklasse <i>Risk Class</i>
EJ126R	UNIVERSAL TROCAR WITH 4 TIPS	I
EJ315R	TILLEY LICHTWITZ ANTRUM TROCAR D:5 FG	I
EJ316R	TILLEY LICHTWITZ ANTRUM TROCAR D:6 FG	I
EJ317R	TILLEY-LICHTWITZ ANTRUM TROCAR D:7 FG	I
EJ318R	TILLEY-LICHTWITZ ANTRUM TROCAR D:8 FG	I
EJ305R	SINUSCOPY TROCAR 5MM 85MM	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:	4039239000001313ZT

Artikelnummer <i>Ref. Number</i>	Bezeichnung <i>Description</i>	Risikoklasse <i>Risk Class</i>
EJ433R	HASSON OBTURATORBLUNTFOR EJ441R D:10MM	I
EJ558R	BLUNT CONICAL OBTURATOR D:10/110MM	I
EJ568R	BLUNT CONICAL OBTURATOR D:10/150MM	I
EJ586R	TRIANGULAR OBTURATOR D:13MM 110MM	I
EJ587R	CONICAL OBTURATOR SHARP D:13MM 110MM	I
EJ588R	CONICAL OBTURATOR BLUNT D:13MM 110MM	I
EJ705R	TROCAR TRI-TIP 5.5MM 60MM	I
EJ706R	TROCAR TAPERED-TIP 5.5MM 60MM	I
EJ715R	TROCAR TRI-TIP 5.5MM 110MM	I
EJ716R	TROCAR TAPERED-TIP 5.5MM 110MM	I
EJ718R	BLUNT CONICAL OBTURATOR 5.5MM110MM LGTH	I
EJ720R	BLUNT CONICAL OBTURATOR D:5.5/150MM	I
EJ725R	TROCAR TRI-TIP 5.5MM 150MM	I
EJ755R	TROCAR TRI-TIP 10MM 110MM	I
EJ756R	TROCAR TAPERED-TIP 10MM 110MM	I
EJ765R	TROCAR TRI-TIP 10MM 150MM	I

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EJ766R	TROCAR TAPERED-TIP 10MM 150MM	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:	4039239000001314ZV	

Artikelnummer <i>Ref. Number</i>	Bezeichnung <i>Description</i>	Risikoklasse <i>Risk Class</i>
EJ475	TROCAR W/TRUMPET VALVE 20MM 110MM LONG	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:	403923900000131522	

Artikelnummer <i>Ref. Number</i>	Bezeichnung <i>Description</i>	Risikoklasse <i>Risk Class</i>
EJ477R	DILATION SET 5.5-10MM	I
EJ480R	DILATION SET 10MM TO 20MM	I
EJ482R	DILATION SET 10MM TO 15MM	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:	4039239000001321ZS	

Artikelnummer <i>Ref. Number</i>	Bezeichnung <i>Description</i>	Risikoklasse <i>Risk Class</i>
EJ807R	CONICAL OBTURATOR 7MM 100MM	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:	4039239000001322ZU	

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Artikelnummer <i>Ref. Number</i>	Bezeichnung <i>Description</i>	Risikoklasse <i>Risk Class</i>
EJ871R	TROCAR BODY F.EJ870P INCL.OBTURATOR	I
EJ872R	TROCAR BODY ONLY W/O OBTURAT.F.EJ870P	I
EJ873R	OBTURATOR ONLY F.EJ870P	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:	4039239000001323ZW

Artikelnummer <i>Ref. Number</i>	Bezeichnung <i>Description</i>	Risikoklasse <i>Risk Class</i>
EK030R	DILATING TROCAR PIN 3.5/70MM	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:	403923900000132423

Artikelnummer <i>Ref. Number</i>	Bezeichnung <i>Description</i>	Risikoklasse <i>Risk Class</i>
EK045R	TROCAR PIN CONICAL SHARP 5/60MM	I
EK046R	TROCAR PIN CONICAL SHARP 5/110MM	I
EK047R	TROCAR PIN CONICAL SHARP 5/150MM	I
EK048R	TROCAR PIN CONICAL BLUNT 5/60MM	I
EK049R	TROCAR PIN CONICAL BLUNT 5/110MM	I
EK050R	TROCAR PIN CONICAL BLUNT 5/150MM	I
EK051R	TROCAR PIN TRIANGULAR 5/60MM	I
EK052R	TROCAR PIN TRIANGULAR 5/110MM	I
EK053R	TROCAR PIN TRIANGULAR 5/150MM	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:	403923900000132525

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Artikelnummer <i>Ref. Number</i>	Bezeichnung <i>Description</i>	Risikoklasse <i>Risk Class</i>
EK056R	TROCAR PIN CONICAL SHARP 10/110MM	I
EK057R	TROCAR PIN CONICAL SHARP 10/150MM	I
EK060R	TROCAR PIN CONICAL BLUNT 10/150MM	I
EK062R	TROCAR PIN TRIANGULAR 10/110MM	I
EK063R	TROCAR PIN TRIANGULAR 10/150MM	I
EK064R	TROCAR PIN BLUNT (HASSON) 10/110MM	I
EK066R	TROCAR PIN CONICAL SHARP 12/110MM	I
EK067R	TROCAR PIN CONICAL SHARP 12/150MM	I
EK069R	TROCAR PIN CONICAL BLUNT 12/110MM	I
EK070R	TROCAR PIN CONICAL BLUNT 12/150MM	I
EK072R	TROCAR PIN TRIANGULAR 12/110MM	I
EK073R	TROCAR PIN TRIANGULAR 12/150MM	I
EK074R	TROCAR PIN BLUNT (HASSON) 12/110MM	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:	403923900000132627

Artikelnummer <i>Ref. Number</i>	Bezeichnung <i>Description</i>	Risikoklasse <i>Risk Class</i>
EK058R	TROCAR PIN CONICAL BLUNT 10/60MM	I
EK059R	TROCAR PIN CONICAL BLUNT 10/110MM	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:	403923900000132729

Artikelnummer <i>Ref. Number</i>	Bezeichnung <i>Description</i>	Risikoklasse <i>Risk Class</i>
EK345R	TROCAR PIN CONICAL SHARP 3.5/60MM	I
EK346R	TROCAR PIN CONICAL SHARP 3.5/110MM	I
EK348R	TROCAR PIN CONICAL BLUNT 3.5/60MM	I
EK349R	TROCAR PIN CONICAL BLUNT 3.5/110MM	I
EK355R	TROCAR PIN CONICAL SHARP 3.5/60MM	I
EK356R	TROCAR PIN CONICAL SHARP 3.5/110MM	I

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EK358R	TROCAR PIN CONICAL BLUNT 3.5/60MM	I
EK359R	TROCAR PIN CONICAL BLUNT 3.5/110MM	I

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