

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. G10 010066 0438

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 and related accessories are used to create and maintain access to the surgical field for instruments and endoscopes during laparoscopic procedures.
Basic-UDI-DI:	403923900000131726

Artikelnummer <i>Ref. Number</i>	Bezeichnung <i>Description</i>	Risikoklasse <i>Risk Class</i>
EJ601R	REDUCING SLEEVE D:10.5 TO 5.5MM	Ila
EJ602R	REDUCING SLEEVE D:13MM TO 5.5MM	Ila
EJ604R	REDUCING SLEEVE D:13MM TO 10MM	Ila
EJ614R	REDUCING SLEEVE D:20.0 TO 10.0MM	Ila
EK090R	REDUCING SLEEVE 10MM TO 5MM	Ila
EK091R	REDUCING SLEEVE 12MM TO 10MM AND 5MM	Ila
PL650R	LOOP APPLIER 4.4MM IN - 5MM OUT	Ila

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:	40392390000013282B

Artikelnummer <i>Ref. Number</i>	Bezeichnung <i>Description</i>	Risikoklasse <i>Risk Class</i>
EJ430R	TROCAR SLEEVE CONE ATTACHMENT 10MM	Ila
EJ432R	CANNULA SHAFT F/HASSON TROCAR 10MM90MM	Ila
EJ441R	HASSON TROCAR COMPLETE10MM 100MM	Ila

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:	40392390000013292D

Artikelnummer <i>Ref. Number</i>	Bezeichnung <i>Description</i>	Risikoklasse <i>Risk Class</i>
EJ580R	TROCAR COMPL.D:13MM 110MM	Ila
EJ582R	CANNULA D:13MM 110MM SMOOTH	Ila
EJ583R	CANNULA D:13MM 110MM SMOOTH W.STOPCOCK	Ila
EJ584R	CANNULA D:13MM 110MM THREADED	Ila
EJ585R	CANNULA D:13MM 110MM THRDED W.STOPCOCK	Ila
EJ701R	CANNULA COMPLETE W/O TROCAR 5.5MM110MM	Ila

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EJ702R	CANNULA SHAFT SMOOTH 5.5MM 60MM	Ila
EJ703R	CANNULA SHAFT THRD 5.5MM 60MM	Ila
EJ712R	CANNULA SHAFT SMOOTH 5.5MM 110MM	Ila
EJ713R	CANNULA SHAFT THRD 5.5MM 110MM	Ila
EJ722R	CANNULA SHAFT SMOOTH 5.5MM 150MM	Ila
EJ751R	CANNULA COMPLETE W/O TROCAR D:10MM 110MM	Ila
EJ752R	CANNULA SHAFT SMOOTH 10MM 110MM	Ila
EJ753R	CANNULA SHAFT THRD 10MM 110MM	Ila
EJ762R	CANNULA SHAFT SMOOTH 10MM 150MM	Ila

Zweckbestimmung Intended Use	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:	4039239000001330ZT

Artikelnummer Ref. Number	Bezeichnung Description	Risikoklasse Risk Class
EJ590R	FLEX.LAP.-TROCAR COMPL.D:13MM 100MM	Ila
EJ595R	FLEX.THORAC.TROCAR COMPL.D:13MM 75MM	Ila
EJ800R	MODULAR FLEXIBLE TROCAR COMPLETE 7.0MM	Ila
EJ804P	FLEXIBLE CANNULA 7MM 75MM LENGTH	Ila
EJ806P	FLEXIBLE CANNULA 7MM 100MM LENGTH	Ila
EJ824P	FLEXIBLE CANNULA 12.5MM 75MM LENGTH	Ila
EJ826P	FLEXIBLE CANNULA 12.5MM 100MM LENGTH	Ila
EJ830R	ENDOSCOPY TROCAR CPL.D:7.0MM 75MM	Ila
EJ831R	TROCAR BODY ONLY W/O VALVE D:7.0MM	Ila

Zweckbestimmung Intended Use	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:	4039239000001331ZV

Artikelnummer Ref. Number	Bezeichnung Description	Risikoklasse Risk Class
EJ704P	TROCAR SHFT PLASTIC W/THRD 5.5MM 60MM	Ila
EJ714P	TROCAR SHAFT PLASTIC W/THREAD 55MM110MM	Ila
EJ754P	TROCAR SHAFT PLAS.W/THREAD 10/110MM LG.	Ila
EJ764P	TROCAR SHAFT PLAST.D:10MM 150MM LG.	Ila

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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:	403923900000133324

Artikelnummer <i>Ref. Number</i>	Bezeichnung <i>Description</i>	Risikoklasse <i>Risk Class</i>
EK010R	TROCAR SLEEVE 5/60MM SMOOTH WITH TAP	Ila
EK011R	TROCAR SLEEVE 5/60MM SMOOTH W/O TAP	Ila
EK012R	TROCAR SLEEVE 5/60MM THREADED WITH TAP	Ila
EK013R	TROCAR SLEEVE 5/60MM THREADED W/O TAP	Ila
EK014R	TROCAR SLEEVE 5/110MM SMOOTH WITH TAP	Ila
EK015R	TROCAR SLEEVE 5/110MM SMOOTH W/O TAP	Ila
EK016R	TROCAR SLEEVE 5/110MM THREADED WITH TAP	Ila
EK017R	TROCAR SLEEVE 5/110MM THREADED W/O TAP	Ila
EK018R	TROCAR SLEEVE 5/150MM SMOOTH WITH TAP	Ila
EK097R	SUTURE FIXATION FOR 5MM TROCARS	Ila

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:	403923900000133426

Artikelnummer <i>Ref. Number</i>	Bezeichnung <i>Description</i>	Risikoklasse <i>Risk Class</i>
EK024R	TROCAR SLEEVE 10/110MM SMOOTH WITH TAP	Ila
EK025R	TROCAR SLEEVE 10/110MM SMOOTH W/O TAP	Ila
EK026R	TROCAR SLEEVE 10/110MM THREADED WITH TAP	Ila
EK027R	TROCAR SLEEVE 10/110MM THREADED W/O TAP	Ila
EK028R	TROCAR SLEEVE 10/150MM SMOOTH WITH TAP	Ila
EK034R	TROCAR SLEEVE 12/110MM SMOOTH WITH TAP	Ila
EK035R	TROCAR SLEEVE 12/110MM SMOOTH W/O TAP	Ila
EK036R	TROCAR SLEEVE 12/110MM THREADED WITH TAP	Ila
EK037R	TROCAR SLEEVE 12/110MM THREADED W/O TAP	Ila
EK038R	TROCAR SLEEVE 12/150MM SMOOTH WITH TAP	Ila

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:	403923900000133528

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Artikelnummer <i>Ref. Number</i>	Bezeichnung <i>Description</i>	Risikoklasse <i>Risk Class</i>
EK043R	TROCAR SLEEVE 10/60MM SMOOTH WITH TAP	Ila
EK044R	TROCAR SLEEVE 10/110MM SMOOTH WITH TAP	Ila

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:	40392390000013362A

Artikelnummer <i>Ref. Number</i>	Bezeichnung <i>Description</i>	Risikoklasse <i>Risk Class</i>
EK080P	SEALING UNIT FOR 5MM TROCARS	Ila
EK081P	CROSS SLIT VALVE FOR 5MM TROCARS	Ila
EK082P	SEALING CAP FOR 5MM TROCARS	Ila

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:	40392390000013372C

Artikelnummer <i>Ref. Number</i>	Bezeichnung <i>Description</i>	Risikoklasse <i>Risk Class</i>
EK083P	SEALING UNIT F/10/12MM TROCARS W.REDUCER	Ila
EK084P	CROSS SLIT VALVE FOR 10/12MM TROCARS	Ila
EK085P	SEALING CAP FOR 10/12MM TROCARS	Ila
EK086P	SEALING UNIT FOR 10/12MM TROCARS	Ila
EK087P	REDUCING CONVERTER 10/12MM TO 5MM	Ila
EK088P	SEALING HOUSING F/10/12MM SEALING UNIT	Ila

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:	40392390000013382E

Artikelnummer <i>Ref. Number</i>	Bezeichnung <i>Description</i>	Risikoklasse <i>Risk Class</i>
EK093P	SEALING CAP F/REDUC.SLEEVE 10/12MM T.5MM	Ila
EK094P	SEALING CAP F/REDUC.SLEEVE 12MM TO 10MM	Ila

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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:	40392390000013392G

Artikelnummer <i>Ref. Number</i>	Bezeichnung <i>Description</i>	Risikoklasse <i>Risk Class</i>
EK098R	CONE FOR 10MM TROCARS	Ila
EK099R	CONE FOR 12MM TROCARS	Ila

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:	403923900000134225

Artikelnummer <i>Ref. Number</i>	Bezeichnung <i>Description</i>	Risikoklasse <i>Risk Class</i>
EK310R	TROCAR SLEEVE 3.5/60MM SMOOTH WITH TAP	Ila
EK311R	TROCAR SLEEVE 3.5/60MM SMOOTH W/O TAP	Ila
EK314R	TROCAR SLEEVE 3.5/110MM SMOOTH WITH TAP	Ila
EK315R	TROCAR SLEEVE 3.5/110MM SMOOTH W/O TAP	Ila
EK397R	SUTURE FIXATION FOR 3.5MM TROCARS	Ila

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:	403923900000134327

Artikelnummer <i>Ref. Number</i>	Bezeichnung <i>Description</i>	Risikoklasse <i>Risk Class</i>
EK380P	SEALING UNIT FOR 3.5MM TROCARS	Ila
EK381P	CROSS SLIT VALVE FOR 3.5MM TROCARS	Ila
EK382P	SEALING CAP FOR 3.5MM TROCARS	Ila

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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:	403923900000134429

Artikelnummer <i>Ref. Number</i>	Bezeichnung <i>Description</i>	Risikoklasse <i>Risk Class</i>
EK390R	REDUCING SLEEVE 5MM TO 3.5MM	Ila
EK391R	SUTURE SLEEVE FOR 3.5MM TROCARS	Ila

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Title: Declaration of Conformity Trocar and accessories Ila.docx Initiator: Anne Katrin ? Wacker

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Date: Wednesday, 22 May 2024, 15:38 W. Europe Daylight Time
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UserName: Schaeuble, Martin (schamnde)
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