

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**.*

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** 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**.*

Benannte Stelle / *Notified Body*:
TÜV SÜD Product Services GmbH, Ridlerstraße 65, 80339 München, Germany
Kennnummer / *Identification number* **0123**

Die **Gültigkeit** der Konformitätserklärung entspricht der Geltungsdauer des aktuell gültigen EG-Zertifikates -
vollständiges QM-System nach Anhang IX, (EU) 2017/745.
***Validity** of the Declaration of Conformity corresponds to the currently valid EC certificate - Full QA System,
Annex IX, (EU) 2017/745.*

i.V.

Martin Schäuble
Vice President R&D

i.V.

Dr. Juliana Vaz Nürnberger
Director Global Regulatory Affairs

Konformitätserklärung Declaration of Conformity

Zweckbestimmung Intended Use	Needle holders are surgical instruments which are intended for the universal use in various surgical disciplines. Needle holders are used for grasping, holding and guiding surgical suture needles and surgical suture material in surgical procedures.
Basic-UDI-DI:	403923900000038128

Artikelnummer Ref. Number	Bezeichnung Description	Risikoklasse Risk Class
BM001R	DUROGRIP CASTROVIEJO NDL HLDR SMTH 145MM	Class I
BM002R	DUROGRIP CASTROV.NDL HLDR SERR 0.2/145MM	Class I
BM003R	DUROGRIP NEEDLEHOLDER 0.4/180MM	Class I
BM004R	DUROGRIP NDL HLDR SERR 0.2/180MM	Class I
BM005R	DUROGRIP CASTROV.NDL HLDR SERR 0.2/215MM	Class I
BM008R	TC DERF NEEDLE HOLDER 120MM	Class I
BM009R	TC MASING NEEDLE HOLDER ANG-RING130MM	Class I
BM010R	TC HALSEY NEEDLE HOLDERDELSMTH120MM	Class I
BM011R	TC CONVERSE NEEDLE HOLDER SERR 130MM	Class I
BM012R	TC HALSEY NEEDLE HOLDER SERR 130MM	Class I
BM013R	TC BABY-CRILE-WOOD NDL HLDR SERR 150MM	Class I
BM014R	TC WEBSTER NEEDLE HOLDER SMOOTH 130MM	Class I
BM015R	TC BAUMGARTNER NDL HLDR HVYSERR145MM	Class I
BM016R	TC CRILE-WOOD NDL HLDRSTRSERR 145MM	Class I
BM017R	TC CRILE-WOOD NDL HLDRSTD SERR185MM	Class I
BM018R	DUROGRIP KILNER NEEDLE HOLDER 135MM	Class I
BM019R	TC CRILE-WOOD NDL HLDRSTD SERR 200MM	Class I
BM020R	TC SAROT NEEDLE HOLDER SERR 180MM	Class I
BM021R	TC CRILE-WOOD NDL HLDRSTD SERR305MM	Class I
BM022R	TC HEGAR-MAYO-SEELEY NEEDLE HOLDER205MM	Class I
BM023R	TC SAROT NEEDLE HOLDER 260MM	Class I
BM024R	TC WEBSTER NEEDLE HOLDER 130MM	Class I
BM025R	TC NEEDLE HOLDER X-DEL SERR 180MM	Class I
BM026R	TC NEEDLE HOLDER X-DEL SERR200MM	Class I
BM027R	TC NEEDLE HOLDER X-DEL SERR 230MM	Class I
BM030R	TC CRILE-WOOD NEEDLE HOLDSTR 270MM	Class I
BM032R	TC DE'BAKEY NEEDLE HOLDER 150MM	Class I
BM033R	TC DE'BAKEY NEEDLE HOLDERDELSERR165MM	Class I
BM034R	TC DE'BAKEY NEEDLE HOLDERDELSERR210MM	Class I
BM035R	TC DE'BAKEY NDL HOLDER DEL SERR 180MM	Class I
BM036R	TC DE'BAKEY NDL HOLDER DEL SERR 230MM	Class I
BM037R	TC DE'BAKEY NDL HOLDER DEL SERR 260MM	Class I
BM038R	TC DE'BAKEY NDL HOLDER DEL SERR 305MM	Class I
BM040R	DUROGRIP NEEDLE HOLDER 305MM	Class I
BM042R	TC WANGENSTEEN NEEDLE HLDR SERR275MM	Class I

Dieses Dokument ist ohne manuelle Unterschrift gültig. Die Freigabe erfolgt über einen elektronischen Unterschrifts-Prozess. / This document is valid without manual signature. It is signed via electronic signature process.

Konformitätserklärung Declaration of Conformity

BM044R	TC RYDER NEEDLE HOLDERDELSERR 135MM	Class I
BM045R	TC RYDER NEEDLE HOLDERDELSERR 175MM	Class I
BM046R	TC RYDER NEEDLE HOLDERDELSERR 195MM	Class I
BM047R	TC RYDER NEEDLE HOLDERDELSERR 265MM	Class I
BM051R	TC DE'BAKEY NDL HLDROFFSET-RINGS 195MM	Class I
BM052R	TC DE'BAKEY NDL HLDROFFSET-RINGS245MM	Class I
BM054R	TC RYDER NEEDLE HOLDERX-DELSERR135MM	Class I
BM055R	TC RYDER NEEDLE HOLDERX-DELSERR155MM	Class I
BM056R	TC RYDER NEEDLE HOLDERX-DELSERR175MM	Class I
BM057R	TC RYDER NEEDLE HOLDERX-DELSERR210MM	Class I
BM058R	DUROGRIP RYDER NEEDLE HOLDER DELIC.230MM	Class I
BM063R	TC DE'BAKEY NDL HOLDERX-DEL-SERR 165MM	Class I
BM064R	TC DE'BAKEY NDL HOLDERX-DEL-SERR 210MM	Class I
BM065R	TC MAYO-HEGAR NDLHOLDERHVYSERR150MM	Class I
BM066R	TC MAYO-HEGAR NDL HOLDERHVYSERR185MM	Class I
BM067R	TC MAYO-HEGAR NDL HOLDERHVYSERR205MM	Class I
BM068R	TC HEGAR-MAYO NDL HOLDERHVYSERR 235MM	Class I
BM069R	TC MAYO-HEGAR NEEDLE HOLDER305MM	Class I
BM070R	TC HEGAR-MAYO NDL HOLDERHVYSERR 265MM	Class I
BM074R	TC RYDER NEEDLE HOLDER SMOOTH 147MM	Class I
BM075R	TC RYDER NEEDLE HOLDER SMOOTH 177MM	Class I
BM076R	TC RYDER NEEDLE HOLDER 225MM	Class I
BM077R	TC HEGAR NEEDLE HOLDER HVY-SERR 205MM	Class I
BM078R	TC HEGAR NEEDLE HOLDER HVY- SERR240MM	Class I
BM081R	TC HEANEY NDL HOLDER CVD SERR 200MM	Class I
BM082R	DUROGRIP NEEDLE HOLDER S-CVD.215MM	Class I
BM084R	TC HEANEY NEEDLE HOLDER CVD 263MM	Class I
BM088R	MORGAN DUROGRIP NDLHLDR 260MM	Class I
BM089R	MULLER DUROGRIP TC NEEDLEHOLDER360MM	Class I
BM090R	TC MASSON NEEDLE HOLDER SERR 265MM	Class I
BM092R	TC FINOCHIETTO NEEDLE HOLDERANG265MM	Class I
BM095R	TC STRATTE NEEDLE HOLDER LAT-ANG210MM	Class I
BM096R	TC STRATTE NDL HOLDER DBLLAT-ANG230MM	Class I
BM100R	DUROGRIP WERTHEIM NEEDLE HOLDER 200MM	Class I
BM101R	WERTHEIM NDLHLDR 240MM	Class I
BM102R	WERTHEIM DUROGRIP NDLHLDR 300MM	Class I
BM105R	TC NEEDLE HOLDER BAYO 275MM	Class I
BM132R	DUROGRIP LICHTENBERG NEEDLE HOLDER 195MM	Class I
BM148R	DUROGRIP MATHIEU NEEDLE HOLD.FINE 140MM	Class I
BM149R	TC MATHIEU NDL HLDIRSTDGRIP/RCHT140MM	Class I
BM150R	DUROGRIP MATHIEU NEEDLE HOLDER FIN.170MM	Class I
BM151R	TC MATHIEU NDL HLDIRSTDGRIP/RCHT170MM	Class I
BM153R	DUROGRIP MATHIEU NEEDLE HOLDER FIN.200MM	Class I

Dieses Dokument ist ohne manuelle Unterschrift gültig. Die Freigabe erfolgt über einen elektronischen Unterschrifts-Prozess. / This document is valid without manual signature. It is signed via electronic signature process.

Konformitätserklärung Declaration of Conformity

BM154R	TC MATHIEU NDL HLDRSTDGRIP/RCHT200MM	Class I
BM156R	TC MATHIEU NDL HLDRHVYGRIP/RCHT200MM	Class I
BM170R	TC ZWEIFEL NDLHLDR 200MM	Class I
BM178R	TC NDL HLDR DBL-ACT HVY 200MM	Class I
BM183R	DUROGRIP TOENNIS NEEDLE HOLDER 180MM	Class I
BM186R	DUROGRIP TOENNIS NEEDLE HOLDER 180MM	Class I
BM191R	DUROGRIP NEEDLE HOLDER W/O.RATCHET 180MM	Class I
BM193R	DUROGRIP NEEDLE HOLDER W/O.RATCHET 200MM	Class I
BM200R	CONVERSE NDLHOLDER LONG GROOVES 130MM	Class I
BM201R	HALSEY NEEDLE HOLDER DEL SMOOTH130MM	Class I
BM202R	WEBSTER NEEDLE HOLDER SMOOTH 125MM	Class I
BM204R	DERF NEEDLE HOLDER SERR 125MM	Class I
BM205R	HALSEY NEEDLE HOLDER DEL SERR130MM	Class I
BM210R	DOYAN NEEDLE HOLDER 125MM	Class I
BM211R	KILNER NEEDLE HOLDER 135MM	Class I
BM215R	BAUMGARTNER NEEDLE HOLDER SERR 145MM	Class I
BM218R	CRILE-WOOD NDLHLDRFINE-SERR150MM	Class I
BM219R	CRILE-MURRAY NEEDLE HOLDER SERR 150MM	Class I
BM220R	CRILE-WOOD NEEDLE HOLDERHVY-SERR160MM	Class I
BM221R	LAWRENCE NEEDLE HOLDERS 150MM	Class I
BM224R	ADSON NEEDLE HOLDER FEN-SERR 180MM	Class I
BM235R	MAYO-HEGAR NEEDLE HOLDER150MM	Class I
BM236R	MAYO-HEGAR NEEDLE HOLDER185MM	Class I
BM237R	MAYO-HEGAR NEEDLE HOLDER200MM	Class I
BM238R	HEGAR-MAYO NEEDLE HOLDER 235MM	Class I
BM240R	HEGAR-MAYO NEEDLE HOLDER 265MM	Class I
BM241R	MAYO-HEGAR NEEDLE HOLDER 160MM	Class I
BM242R	MAYO-HEGAR NEEDLE HOLDER 190MM	Class I
BM245R	HEGAR NEEDLE HOLDER HVY-SERR 150MM	Class I
BM247R	HEGAR NEEDLE HOLDER HVY-SERR175MM	Class I
BM249R	HEGAR NEEDLE HOLDER HVY-SERR205MM	Class I
BM255R	HEGAR NEEDLE HOLDER HVY-SERR 205MM	Class I
BM259R	HEANEY NEEDLE HOLDER CVD SERR200MM	Class I
BM270R	JAMESON NEEDLE HOLDER DEL SERR 230MM	Class I
BM272R	WANGENSTEEN NEEDLE HOLDER SERR 275MM	Class I
BM275R	MASSON NDL HLDR HVY-SERRGROOVE265MM	Class I
BM280R	NDL HLDRW/OFFSET-SHANKFEM-SERR255MM	Class I
BM301R	DIADUST NEEDLEHOLDER STR 140MM	Class I
BM302R	DIADUST NEEDLEHOLDER STR 180MM	Class I
BM325R	DIADUST NEEDLEHOLDER STR.160MM	Class I
BM327R	DIADUST NEEDLEHOLDER STR.220MM	Class I
BM328R	DIADUST NEEDLEHOLDER STR.250MM	Class I
BM360R	MATHIEU NDL HLDRGRIP/RCHT SERR 140MM	Class I

Dieses Dokument ist ohne manuelle Unterschrift gültig. Die Freigabe erfolgt über einen elektronischen Unterschrifts-Prozess. / This document is valid without manual signature. It is signed via electronic signature process.

Konformitätserklärung Declaration of Conformity

BM361R	MATHIEU NDL HLDRGRIP/RCHT SERR170MM	Class I
BM362R	MATHIEU NDL HLDR GRIP/RCHT SERR 200MM	Class I
BM503R	CRILE NEEDLE HOLDER GRIP150MM	Class I
BM510R	TOENNIS ELASTIC NDL HOLDER GRIP180MM	Class I
BM560R	BARRAQUER NDL HLDR CVD W/RCHT 120MM	Class I
BM562R	BARRAQUER NDL HLDR CVDW/O RCHT120MM	Class I
BM563R	CASTROVIEJO NDL HLDRSTRW/CATCH 145MM	Class I
BM564R	CASTROVIEJO NDL HLDR CVDW/CATCH 145MM	Class I
FD045R	JACOBSON NEEDLE HOLDER STR 185MM	Class I
FD046R	JACOBSON NEEDLE HLDRW/CATCHSTR 185MM	Class I
FD048R	MICRO NEEDLEHOLDER STR.200MM	Class I
FD076R	MICRO NEEDLE HLDR W/O CATCHSTR160MM	Class I
FD079R	MICRO NEEDLE HOLDERW/O CATCHCVD160MM	Class I
FD080R	MICRO-NEEDLE HLDR STR FLAT-HDL185MM	Class I
FD081R	MICRO-NEEDLE HLDR CVD FLAT-HDL185MM	Class I
FD230R	BARRAQUER NDL HLDRW/O CATCH STR120MM	Class I
FD231R	BARRAQUER NDL HLDRW/O CATCH CVD120MM	Class I
FD232R	BARRAQUER NEEDLE HLDRW/CATCHSTR120MM	Class I
FD233R	BARRAQUER NEEDLE HLDRW/CATCHCVD120MM	Class I
FD240R	REILL MICRO NEEDLE HOLDER STR150MM	Class I
FD241R	REILL MICRO NEEDLE HOLDER CVD150MM	Class I
FD242R	MICRO NEEDLEHOLDER 150MM STR.W/RATCHET	Class I
FD243R	MICRO-NEEDLE HOLDER W/CATCH CVD 150MM	Class I
FD244R	MICRO-NEEDLE HLDR STR RND-HDL 185MM	Class I
FD245R	MICRO-NEEDLE HLDR CVD RND-HDL 185MM	Class I
FD246R	MICRO-NEEDLE HLDR W/CATCH STR 185MM	Class I
FD247R	MICRO-NEEDLE HLDR W/CATCH CVD185MM	Class I
FD258R	MICRO NDLHLDR DIAM.COATED180MM STR	Class I
FD259R	MICRO NDLHLDR DIAM.COATED180MMCVD	Class I
FM021R	MUELLER NEEDLE HOLDER W/LOCKCVD145MM	Class I
MB213R	TC MICRO NDL HLDR RND HNDL STR 200MM	Class I
MB606R	DUROGRIP FRENCH EYE NEEDLEHOLDER 160MM	Class I
MB607R	DUROGRIP FRENCH EYE NEEDLEHOLDER 185MM	Class I
MB611R	DUROGRIP FRENCH EYE NEEDLEHOLDER 205MM	Class I
MB612R	DUROGRIP FRENCH EYE NEEDLEHOLDER 235MM	Class I

Dieses Dokument ist ohne manuelle Unterschrift gültig. Die Freigabe erfolgt über einen elektronischen Unterschrifts-Prozess. / This document is valid without manual signature. It is signed via electronic signature process.

Konformitätserklärung *Declaration of Conformity*

Zweckbestimmung <i>Intended Use</i>	Needle holders are surgical instruments which are intended for the universal use in various surgical disciplines. Needle holders are used for grasping, holding and guiding surgical suture needles and surgical suture material in surgical procedures. The scissor part can be used to cut the suture material.
Basic-UDI-DI:	403923900000180625

Artikelnummer <i>Ref. Number</i>	Bezeichnung <i>Description</i>	Risikoklasse <i>Risk Class</i>
BM124R	TC HEGAR-OLSEN NDL HLDR/SCISS 165MM	Class I
BM127R	TC LEWINN NDL HOLDER/SCISSMOOTH 125MM	Class I
BM128R	TC HEGAR-OLSEN NDL HLDR/SCISS 145MM	Class I
BM129R	TC GILLIES NDLHLDR/SCISANGW/EYE160MM	Class I
BM290R	HEGAR-OLSEN NDL HLDR/SCISS SERR 140MM	Class I
BM291R	HEGAR-OLSEN NDL HLDR/SCISS SERR 185MM	Class I
BM298R	GILLIES NEEDLE HOLDER SM P.W.SCISSORS	Class I
BM299R	GILLIES NEEDLE HOLDER/SCISS SERR160MM	Class I

Dieses Dokument ist ohne manuelle Unterschrift gültig. Die Freigabe erfolgt über einen elektronischen Unterschrifts-Prozess. / *This document is valid without manual signature. It is signed via electronic signature process.*

Title: Declaration of Conformity MDR_T&V S&D_Needle Holders_Class I(r).docx Initiator: Sandra ? Bury

This document is signed electronically in compliance with the B. Braun electronic signature policies and procedures by following persons:

UserName: Bury, Sandra (burysade)
Title: Regulatory Affairs Manager
Date: Friday, 09 October 2020, 15:50 W. Europe Daylight Time
Meaning: Document signed as Author

UserName: Schaeuble, Martin (schamnde)
Title: Vice President R&D Abdominal & Cardio-Thoracic Surgery
Date: Friday, 09 October 2020, 18:35 W. Europe Daylight Time
Meaning: Approve Document

UserName: Vaz Nuernberger, Juliana (vaznjude)
Title: Director Global Regulatory Affairs
Date: Saturday, 10 October 2020, 12:41 W. Europe Daylight Time
Meaning: Approve Document
