

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, 2020-07-10

i.V.

Martin Schäuble
Vice President R&D
R&D Abdominal & Cardio-Thoracic Surgery &
Product Maintenance

i.V.

Juliana Vaz Nürnberger
Director Global Regulatory Affairs

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Zweckbestimmung <i>Intended Use</i>	In general, the dental filling-instruments are the instruments that are used to remove excess filling material in endodontics and filling treatment.
Basic-UDI-DI:	40392390000055027

Artikelnummer <i>Ref. Number</i>	Bezeichnung <i>Description</i>
DB409R	SPOON CURETTE F.MICROENDODONTIA
DB411R	MICRODISSECTOR 1/1.4MM BR.F.MICROENDOD.
DC400R	ERGOFILL WILAND CARVER
DE006R	PLASTIC FILLING INSTRUMENT 0.8MM 170MM
DE007R	PLASTIC FILLING INSTRUMENT EXAXIAL
DE030R	PLASTIC FILLING INSTRUMENT EXAXIAL
DE031R	PLASTIC FILLING INSTRUMENT EXAXIAL
DE032R	PLASTIC FILLING INSTRUMENT EXAXIAL
DE050R	ROUND CONDENSER W/ERGONMIC HDL.GREEN
DE051R	ROUND CONDENSER W/ERGONMIC HDL.GREEN
DE052R	ROUND CONDENSER W/ERGONMIC HDL.GREEN
DE053R	ROUND CONDENSER W/ERGONMIC HDL.GREEN
DE054R	ROUND CONDENSER W/ERGONMIC HDL.GREEN
DE055R	ROUND CONDENSER W/ERGONMIC HDL.GREEN
DE059R	THREE ANG.RND COND.ERGONM.HDL.GREEN
DE060R	THREE ANG.RND COND.ERGONM.HDL.GREEN
DE125R	PLASTIC FILLING INSTRUMENT CONTRA ANGLE
DE126R	PLASTIC FILLING INSTRUMENT CONTRA ANGLE
DE127R	PLASTIC FILLING INSTRUMENT CONTRA ANGLE
DE134R	PLASTIC FILLING INSTRUMENT CONTRA ANGLE
DE135R	PLASTIC FILLING INSTRUMENT CONTRA ANGLE
DE136R	PLASTIC FILLING INSTRUMENT CONTRA ANGLE
DE292R	WOODSON PLASTIC FILLING INSTRUMENT #2
DE297R	WALLIS PLASTIC FILLING INSTR.DBL.END.
DE305R	HOPSON PLASTIC FILLING INSTR.DBL.END.

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DE307R	FILLING INSTRUMENT #M7
DE420R	HEIDEMANN PLASTIC FILLING INSTRUMENT
DE421R	HEIDMANN PLASTIC FILLING INSTRUMENT
DE424R	HOLLENBACK PLASTIC FILLING INSTRUMENT
DE425R	WARD 1 PLASTIC FILLING INSTRUMENT
DE427R	FILLING INSTRUMENT HOLLENBACK 1/2 L7
DE440R	ROUND CONDENSER/SPATULA F.MICROENDODONT.
DE442R	CONDENSER OVAL F.MICROENDODONTIA
DE443R	CONDENSER ROUND F.MICROENDODONTIA
DE444R	CONDENSER ROUND 90°ANGLE
DE445R	CONDENSER ROUND F.MICRO ENDODONTIA
DE446R	PLUGGER ROUND 175MM
DE621R	BLACK AMALGAM PLUGGER
DE622R	AMALGAM PLUGGER DBL 3.0MM2.5MM170MM
DE671R	FILLING INSTRUMENT HOLLENBACK #1
DE672R	FILLING INSTRUMENT HOLLENBACK #2
DE808R	ERGOFILL BALL-PT.PLUGGER CONTRA ANG.MED.
DE809R	ERGOFILL BALL-PT.PLUGGER CONTRA ANG.LRG.
DE820R	ERGOFILL HEIDEMANN SPATULA
DE821R	ERGOFILL HEIDEMANN SPATULA MEDIUM
DE822R	ERGOFILL HEIDEMANN SPATULA LARGE
DE917R	ERGOFILL BALL-PT.PLUGGER THREE-ANG.SMALL
DE919R	ERGOFILL BALL-PT.PLUGGER THREE-ANG.LARGE
DF061R	BURNISHING INSTR.F.AMALGAM DBL.ENDED
DF078R	COMPOSITE MOULDING INSTRUMENT #2
DF079R	COMPOSITE MOULDING INSTRUMENT #3
DF082R	COMPOSITE CARVING INSTRUMENT
DF084R	COMPOSITE PLUGGER
DF086R	HEIDEMANN COMPOSITE SPATULA
DF088R	COMPOSITE ROUND CONDENSER
DF138R	CEMENT SPATULA SINGLEENDED
DF150R	CEMENT SPATULA DOUBLEENDED
DF153R	CEMENT SPATULA DOUBLEENDED
DF161R	CEMENT SPATULA DOUBLEENDED
DF163R	CEMENT SPATULA DOUBLEENDED
DF165R	CEMENT SPATULA DOUBLEENDED
DF581R	ERGOFILL MOULDING INSTRUMENT

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Effective

DF582R	ERGOFILL MOULDING INSTRUMENT
DF583R	ERGOFILL MOULDING INSTRUMENT

Effective

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