

# 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*:  
09.07.2025

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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|---------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Zweckbestimmung</b><br><i>Intended Purpose</i> | In general, the dental filling-instruments are the instruments that are used to remove excess filling material in endodontics and filling treatment. |
| <b>Basic-UDI-DI:</b>                              | 403923900000055027                                                                                                                                   |

| <b>Artikelnummer</b><br><i>Ref. Number</i> | <b>Bezeichnung</b><br><i>Description</i> | <b>Risikoklasse</b><br><i>Risk Class</i> |
|--------------------------------------------|------------------------------------------|------------------------------------------|
| DB409R                                     | SPOON CURETTE F.MICROENDODONTIA          | I                                        |
| DB411R                                     | MICRODISSECTOR 1/1.4MM BR.F.MICROENDOD.  | I                                        |
| DC400R                                     | ERGOFILL WILAND CARVER                   | I                                        |
| DE006R                                     | PLASTIC FILLING INSTRUMENT 0.8MM 170MM   | I                                        |
| DE007R                                     | PLASTIC FILLING INSTRUMENT EXAXIAL       | I                                        |
| DE030R                                     | PLASTIC FILLING INSTRUMENT EXAXIAL       | I                                        |
| DE031R                                     | PLASTIC FILLING INSTRUMENT EXAXIAL       | I                                        |
| DE032R                                     | PLASTIC FILLING INSTRUMENT EXAXIAL       | I                                        |
| DE050R                                     | ROUND CONDENSER W/ERGONMIC HDL.GREEN     | I                                        |
| DE052R                                     | ROUND CONDENSER W/ERGONMIC HDL.GREEN     | I                                        |
| DE053R                                     | ROUND CONDENSER W/ERGONMIC HDL.GREEN     | I                                        |
| DE054R                                     | ROUND CONDENSER W/ERGONMIC HDL.GREEN     | I                                        |
| DE059R                                     | THREE ANG.RND COND.ERGONM.HDL.GREEN      | I                                        |
| DE060R                                     | THREE ANG.RND COND.ERGONM.HDL.GREEN      | I                                        |
| DE125R                                     | PLASTIC FILLING INSTRUMENT CONTRA ANGLE  | I                                        |
| DE126R                                     | PLASTIC FILLING INSTRUMENT CONTRA ANGLE  | I                                        |
| DE127R                                     | PLASTIC FILLING INSTRUMENT CONTRA ANGLE  | I                                        |
| DE134R                                     | PLASTIC FILLING INSTRUMENT CONTRA ANGLE  | I                                        |
| DE135R                                     | PLASTIC FILLING INSTRUMENT CONTRA ANGLE  | I                                        |
| DE136R                                     | PLASTIC FILLING INSTRUMENT CONTRA ANGLE  | I                                        |
| DE292R                                     | WOODSON PLASTIC FILLING INSTRUMENT #2    | I                                        |
| DE297R                                     | WALLIS PLASTIC FILLING INSTR.DBL.END.    | I                                        |
| DE305R                                     | HOPSON PLASTIC FILLING INSTR.DBL.END.    | I                                        |
| DE307R                                     | FILLING INSTRUMENT #M7                   | I                                        |
| DE420R                                     | HEIDEMANN PLASTIC FILLING INSTRUMENT     | I                                        |
| DE421R                                     | HEIDMANN PLASTIC FILLING INSTRUMENT      | I                                        |
| DE424R                                     | HOLLENBACK PLASTIC FILLING INSTRUMENT    | I                                        |
| DE425R                                     | WARD 1 PLASTIC FILLING INSTRUMENT        | I                                        |
| DE427R                                     | FILLING INSTRUMENT HOLLENBACK 1/2 L7     | I                                        |
| DE440R                                     | ROUND CONDENSER/SPATULA F.MICROENDODONT. | I                                        |
| DE442R                                     | CONDENSER OVAL F.MICROENDODONTIA         | I                                        |
| DE443R                                     | CONDENSER ROUND F.MICROENDODONTIA        | I                                        |
| DE444R                                     | CONDENSER ROUND 90°ANGLE                 | I                                        |
| DE445R                                     | CONDENSER ROUND F.MICRO ENDODONTIA       | I                                        |
| DE446R                                     | PLUGGER ROUND 175MM                      | I                                        |
| DE621R                                     | BLACK AMALGAM PLUGGER                    | I                                        |
| DE622R                                     | AMALGAM PLUGGER DBL 3.0MM2.5MM170MM      | I                                        |
| DE671R                                     | FILLING INSTRUMENT HOLLENBACK #1         | I                                        |

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|        |                                          |  |
|--------|------------------------------------------|--|
| 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 SMALL         |  |
| 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 DBLEND        |  |
| 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 DBLEND.                   |  |
| DF153R | CEMENT SPATULA DBLEND.                   |  |
| DF161R | CEMENT SPATULA DBLEND.                   |  |
| DF163R | CEMENT SPATULA DBLEND.                   |  |
| DF165R | CEMENT SPATULA DBLEND.                   |  |
| DF581R | ERGOFILL MOULDING INSTRUMENT             |  |
| DF582R | ERGOFILL MOULDING INSTRUMENT             |  |
| DF583R | ERGOFILL MOULDING INSTRUMENT             |  |

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Data ID: 149026207 - Version: 2.0 - Document ID: BDoCS-AIM-031568 - Effective Date: 2025-01-07

Viewed by: BBMAG\_Service, SSC-FI-SAS\_RPA\_QM01 (s080a6de) - Document as a print out invalid 24h after: 2025-02-12 18:05 (CET)

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Title: DoC\_Dental\_Filling Instruments Initiator: Sandra ? Bury

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