

## Konformitätserklärung *Declaration of Conformity*

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** 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*:  
**MEDCERT GmbH**, Pilatuspool 2, 20355 Hamburg, Germany  
Kennnummer / *Identification number* **0482**

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.

Michaela Münnig  
Vice President R&D

i.V.

Matthias Welke  
Director Global Regulatory Affairs

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## Konformitätserklärung Declaration of Conformity

<b>Zweckbestimmung</b> <i>Intended Use</i>	<p>The implant is used</p> <ul style="list-style-type: none"> <li>■ as a component of a human hip endoprosthesis: Hip endoprosthesis stem</li> <li>■ in combination with Aesculap hip endoprosthesis components</li> <li>■ in combination with implant components explicitly approved by Aesculap</li> <li>■ for implantation without bone cement</li> </ul> <p>The implant range consists of Metha® 120°, 130° and 135° hip stems.</p> <p>Note</p> <p>The options for patient-specific care depend on the available implant components. Implant dimensions and any possible combinations in individual cases can be found in the operating technique instructions for the individual systems.</p>
<b>Basic-UDI-DI:</b>	<b>403923900000170029</b>

<b>Artikelnummer</b> <i>Ref. Number</i>	<b>Bezeichnung</b> <i>Description</i>	<b>Risikoklasse</b> <i>Risk Class</i>
NC270T	METHA µCAP 12/14 130°/0° SIZE 0	III
NC271T	METHA µCAP 12/14 130°/0° SIZE 1	III
NC272T	METHA µCAP 12/14 130°/0° SIZE 2	III
NC273T	METHA µCAP 12/14 130°/0° SIZE 3	III
NC274T	METHA µCAP 12/14 130°/0° SIZE 4	III
NC275T	METHA µCAP 12/14 130°/0° SIZE 5	III
NC276T	METHA µCAP 12/14 130°/0° SIZE 6	III
NC277T	METHA µCAP 12/14 130°/0° SIZE 7	III
NC280T	METHA µCAP 12/14 135°/0° SIZE 0	III
NC281T	METHA µCAP 12/14 135°/0° SIZE 1	III
NC282T	METHA µCAP 12/14 135°/0° SIZE 2	III
NC283T	METHA µCAP 12/14 135°/0° SIZE 3	III
NC284T	METHA µCAP 12/14 135°/0° SIZE 4	III
NC285T	METHA µCAP 12/14 135°/0° SIZE 5	III
NC286T	METHA µCAP 12/14 135°/0° SIZE 6	III
NC287T	METHA µCAP 12/14 135°/0° SIZE 7	III
NC290T	METHA µCAP 12/14 120°/0° SIZE 0	III
NC291T	METHA µCAP 12/14 120°/0° SIZE 1	III
NC292T	METHA µCAP 12/14 120°/0° SIZE 2	III
NC293T	METHA µCAP 12/14 120°/0° SIZE 3	III
NC294T	METHA µCAP 12/14 120°/0° SIZE 4	III
NC295T	METHA µCAP 12/14 120°/0° SIZE 5	III
NC296T	METHA µCAP 12/14 120°/0° SIZE 6	III
NC297T	METHA µCAP 12/14 120°/0° SIZE 7	III

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Title: Metha Implants\_DoC.docx Initiator: Sabine ? Nassal

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