

## EU Technical Documentation Assessment Certificate

### The Notified Body

**MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH**  
**Pilatuspool 2 – 20355 Hamburg – Germany**

herewith certifies that the company

**Aesculap AG**  
**Am Aesculap-Platz**  
**78532 Tuttlingen**  
**Germany**

**SRN: DE-MF-000005504**

has established and maintains a technical documentation for the medical devices listed in the appendix.

The compliance of this technical documentation to the requirements of the  
**Regulation (EU) 2017/745 on medical devices** was verified by assessment according to:

### Annex IX Chapter II

Any applicable limitations of this certification for certain medical devices are included in the appendix. This certificate assumes that MEDCERT has to be informed about any changes of the assessed device. Changes need further approval by MEDCERT.

**Effective date:** 2021-11-05  
**Expiry date:** 2026-11-04

Final assessment report No.: 20220IA01F  
Procedure No.: PP – 20220  
Certificate No.: 20220GB450211105

Preceding certificate No.: —  
Preceding certificate date: —  
Identification of changes: —

For conditions or for limitations to the validity refer to the relevant final assessment report. Examinations and tests performed, e. g. reference to relevant common specifications, harmonised standards, test reports and audit report(s) are recorded in the relevant reports. For placing on the market of the medical devices covered by this certificate, an additional EU Quality Management System Certificate according to Annex IX Chapter I of Regulation (EU) 2017/745 is required.

Hamburg, 2021-11-05

  
MEDCERT Certification Body  
(Lorenz Runge)

The certificate is only valid when provided entirely with all of its pages.  
To verify the validity of this certificate, contact [info@medcert.de](mailto:info@medcert.de).



Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
[www.zlg.de](http://www.zlg.de)

BS-MDR-096

MEDCERT Notified Body Identification Number: 0482

## Appendix of EU Technical Documentation Assessment Certificate

Procedure No.: PP — 20220

Certificate No.: 20220GB450211105

**Class:** III

**Basic UDI-DI:** 403923900000170029

### Intended purpose:

The implant is used ■ as a component of a human hip endoprosthesis: Hip endoprosthesis stem ■ in combination with Aesculap hip endoprosthesis components ■ in combination with implant components explicitly approved by Aesculap ■ for implantation without bone cement. The implant range consists of Metha® 120°, 130° and 135° hip stems. Note: 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.

Model (Device REF#)	Device name
NC270T	METHA µCAP 12/14 130°/0° SIZE 0
NC271T	METHA µCAP 12/14 130°/0° SIZE 1
NC272T	METHA µCAP 12/14 130°/0° SIZE 2
NC273T	METHA µCAP 12/14 130°/0° SIZE 3
NC274T	METHA µCAP 12/14 130°/0° SIZE 4
NC275T	METHA µCAP 12/14 130°/0° SIZE 5
NC276T	METHA µCAP 12/14 130°/0° SIZE 6
NC277T	METHA µCAP 12/14 130°/0° SIZE 7
NC280T	METHA µCAP 12/14 135°/0° SIZE 0
NC281T	METHA µCAP 12/14 135°/0° SIZE 1
NC282T	METHA µCAP 12/14 135°/0° SIZE 2
NC283T	METHA µCAP 12/14 135°/0° SIZE 3
NC284T	METHA µCAP 12/14 135°/0° SIZE 4
NC285T	METHA µCAP 12/14 135°/0° SIZE 5
NC286T	METHA µCAP 12/14 135°/0° SIZE 6
NC287T	METHA µCAP 12/14 135°/0° SIZE 7
NC290T	METHA µCAP 12/14 120°/0° SIZE 0
NC291T	METHA µCAP 12/14 120°/0° SIZE 1
NC292T	METHA µCAP 12/14 120°/0° SIZE 2
NC293T	METHA µCAP 12/14 120°/0° SIZE 3
NC294T	METHA µCAP 12/14 120°/0° SIZE 4
NC295T	METHA µCAP 12/14 120°/0° SIZE 5
NC296T	METHA µCAP 12/14 120°/0° SIZE 6
NC297T	METHA µCAP 12/14 120°/0° SIZE 7

This appendix is integral part of the above-referenced certificate.  
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