

EU Technical Documentation Assessment Certificate

Certificate no.
13685GB450221103A

Final assessment report no.
13685AU04F

Effective date
2022-11-03

Expiry date
2027-11-02

This is to certify that
Medical devices listed on the following pages

Manufactured by

Aesculap AG

Am Aesculap-Platz, 78532 Tuttlingen, Germany

SRN: DE-MF-000005504

Have been assessed and found to comply with respect to

**Technical Documentation Assessment as described in Annex IX
Chapter II of Regulation (EU) 2017/745 on Medical Devices**

Any applicable limitations for certain medical devices are included in the following list or recorded in the final assessment report. This certificate assumes that DNV MEDCERT has to be informed about any changes of the assessed device. Changes need further approval by DNV MEDCERT.

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.

Place and date
Hamburg, 2022-11-03



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
BS-MDR-096

For the issuing office
DNV MEDCERT GmbH – Notified Body 0482
Pilatuspool 2, 20355 Hamburg, Germany


Lorenz Runge
Director Certification Body

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

Lack of fulfilment of conditions as set out in the Certification Agreement may render this Certificate invalid.

820113 EN Rev 4 2022.10.17

NOTIFIED BODY 0482: DNV MEDCERT GmbH (previously: MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH)
Pilatuspool 2, 20355 Hamburg, Germany, Tel +49 40 2263325-0, www.med-cert.com, www.dnv.com

Products covered by this certificate

Class	III
Basic UDI-DI	4039239000002300ZR
Intended purpose	TA016116: 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 with PLASMAPORE® or PLASMAPORE® µ-CaP coated stems ■ for implantation with bone cement, for uncoated stems. The implant range consists of BICONTACT® S, H, SD, E, EH. 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 (REF#)	Device name
NJ609T	BICONTACT E PLASMAPORE-µCAP 8/10 SIZE 9
NJ610T	BICONTACT E PLASMAPORE-µCAP 8/10 SIZE 10
NJ611T	BICONTACT E PLASMAPORE-µCAP 8/10 SIZE 11
NJ612T	BICONTACT E PLASMAPORE-µCAP 8/10 SIZE 12
NJ613T	BICONTACT E PLASMAPORE-µCAP 8/10 SIZE 13
NJ614T	BICONTACT E PLASMAPORE-µCAP 8/10 SIZE 14
NJ615T	BICONTACT E PLASMAPORE-µCAP 8/10 SIZE 15
NJ616T	BICONTACT E PLASMAPORE-µCAP 8/10 SIZE 16
NJ617T	BICONTACT E PLASMAPORE-µCAP 8/10 SIZE 17
NJ618T	BICONTACT E PLASMAPORE-µCAP 8/10 SIZE 18
NJ619T	BICONTACT E PLASMAPORE-µCAP 8/10 SIZE 19
NJ620T	BICONTACT E PLASMAPORE-µCAP 8/10 SIZE 20
NJ628T	BICONTACT E PLASMAPORE-µCAP 8/10 SZ.8H
NJ629T	BICONTACT E PLASMAPORE-µCAP 8/10 SZ.9H
NJ630T	BICONTACT E PLASMAPORE-µCAP 8/10 SZ.10H
NJ631T	BICONTACT E PLASMAPORE-µCAP 8/10 SZ.11H
NJ632T	BICONTACT E PLASMAPORE-µCAP 8/10 SZ.12H
NJ633T	BICONTACT E PLASMAPORE-µCAP 8/10 SZ.13H
NJ634T	BICONTACT E PLASMAPORE-µCAP 8/10 SZ.14H
NJ635T	BICONTACT E PLASMAPORE-µCAP 8/10 SZ.15H
NJ636T	BICONTACT E PLASMAPORE-µCAP 8/10 SZ.16H
NJ637T	BICONTACT E PLASMAPORE-µCAP 8/10 SZ.17H
NJ638T	BICONTACT E PLASMAPORE-µCAP 8/10 SZ.18H
NJ639T	BICONTACT E PLASMAPORE-µCAP 8/10 SZ.19H
NJ640T	BICONTACT E PLASMAPORE-µCAP 8/10 SZ.20H



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Class	III
Basic UDI-DI	4039239000002302ZV
Intended purpose	TA016116: 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 with PLASMAPORE® or PLASMAPORE® µ-CaP coated stems ■ for implantation with bone cement, for uncoated stems. The implant range consists of BiCONTACT® S, H, SD, E, EH. 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 (REF#)	Device name
NK110T	BICONTACT H PLASMAPORE 12/14 SIZE 10MM
NK111T	BICONTACT H PLASMAPORE 12/14 SIZE 11MM
NK112T	BICONTACT H PLASMAPORE 12/14 SIZE 12MM
NK113T	BICONTACT H PLASMAPORE 12/14 SIZE 13MM
NK114T	BICONTACT H PLASMAPORE 12/14 SIZE 14MM
NK115T	BICONTACT H PLASMAPORE 12/14 SIZE 15MM
NK116T	BICONTACT H PLASMAPORE 12/14 SIZE 16MM
NK117T	BICONTACT H PLASMAPORE 12/14 SIZE 17MM
NK118T	BICONTACT H PLASMAPORE 12/14 SIZE 18MM
NK119T	BICONTACT H PLASMAPORE 12/14 SIZE 19MM
NK121T	BICONTACT H PLASMAPORE 12/14 SIZE 21MM
NK508T	BICONTACT S PLASMAPORE 12/14 SIZE 8MM
NK509T	BICONTACT S PLASMAPORE 12/14 SIZE 9MM
NK510T	BICONTACT S PLASMAPORE 12/14 SIZE 10MM
NK511T	BICONTACT S PLASMAPORE 12/14 SIZE 11MM
NK512T	BICONTACT S PLASMAPORE 12/14 SIZE 12MM
NK513T	BICONTACT S PLASMAPORE 12/14 SIZE 13MM
NK514T	BICONTACT S PLASMAPORE 12/14 SIZE 14MM
NK515T	BICONTACT S PLASMAPORE 12/14 SIZE 15MM
NK516T	BICONTACT S PLASMAPORE 12/14 SIZE 16MM
NK517T	BICONTACT S PLASMAPORE 12/14 SIZE 17MM
NK518T	BICONTACT S PLASMAPORE 12/14 SIZE 18MM
NK519T	BICONTACT S PLASMAPORE 12/14 SIZE 19MM
NK520T	BICONTACT S PLASMAPORE 12/14 SIZE 20MM
NK521T	BICONTACT S PLASMAPORE 12/14 SIZE 21MM
NK709T	BICONTACT SD PLASMAPORE 12/14 SIZE 9MM
NK710T	BICONTACT SD PLASMAPORE 12/14 SIZE 10MM
NK711T	BICONTACT SD PLASMAPORE 12/14 SIZE 11MM
NK712T	BICONTACT SD PLASMAPORE 12/14 SIZE 12MM
NK713T	BICONTACT SD PLASMAPORE 12/14 SIZE 13MM
NK714T	BICONTACT SD PLASMAPORE 12/14 SIZE 14MM
NK715T	BICONTACT SD PLASMAPORE 12/14 SIZE 15MM
NK716T	BICONTACT SD PLASMAPORE 12/14 SIZE 16MM



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Class	III
Basic UDI-DI	403923900000230322
Intended purpose	TA016116: 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 with PLASMAPORE® or PLASMAPORE® µ-CaP coated stems ■ for implantation with bone cement, for uncoated stems. The implant range consists of BiCONTACT® S, H, SD, E, EH. 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 (REF#)	Device name
NK312K	BICONTACT H COCR CEMENTED 12/14 SZ.12MM
NK314K	BICONTACT H COCR CEMENTED 12/14 SZ.14MM
NK316K	BICONTACT H COCR CEMENTED 12/14 SZ.16MM
NK318K	BICONTACT H COCR CEMENTED 12/14 SZ.18MM
NK610K	BICONTACT S COCR CEMENTED 12/14 SZ.10MM
NK612K	BICONTACT S COCR CEMENTED 12/14 SZ.12MM
NK614K	BICONTACT S COCR CEMENTED 12/14 SZ.14MM
NK616K	BICONTACT S COCR CEMENTED 12/14 SZ.16MM
NK618K	BICONTACT S COCR CEMENTED 12/14 SZ.18MM

Class	III
Basic UDI-DI	403923900000230424
Intended purpose	TA009501: The implant is used as a component of a human hip endoprosthesis compatible with the BICONTACT SD and PLASMACUP SC implant and instrument system. Implant components: ■ SDC = BICONTACT® SD compatible hip stem, cementless ■ SDC modular heads, 28 mm in different neck length ■ PLC = PLASMACUP® SC compatible pressfit cup, cementless ■ The SDC stem and head implant components are packed individually; each has an individual reference number. ■ The PLC pressfit-cup is packed together with an 28 mm posterior wall polyethylene insert and 6.5 mm titanium fixation screws ■ Combinations of implants of the SDC and PLC series with Aesculap hip endoprosthesis components only. Note: The ability to treat patient individual deficiencies is dependent on the available implant components. Implant dimensions and possible combinations for the individual case are given in the operating instructions for the respective system.
Model (REF#)	Device name
NK700T	SDC HIP PROSTH.CEMENTLESS 12/14 SZ.10MM
NK701T	SDC HIP PROSTH.CEMENTLESS 12/14 SZ.11MM
NK702T	SDC HIP PROSTH.CEMENTLESS 12/14 SZ.12MM
NK703T	SDC HIP PROSTH.CEMENTLESS 12/14 SZ.13MM
NK704T	SDC HIP PROSTH.CEMENTLESS 12/14 SZ.14MM
NK705T	SDC HIP PROSTH.CEMENTLESS 12/14 SZ.15MM