

## 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, Kapitel I** 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, Chapter I**.*

Benannte Stelle / Notified Body: DVN MEDCERT GmbH, Pilatuspool 2, 20355 Hamburg, Germany  
Kennnummer / Identification number: 0482

EU Technical Documentation Assessment Certificate – Regulation (EU) 2017/745 Annex IX Chapter II –  
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Tuttlingen, Germany

i.V.

i.V.

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SA-DE13-M-4-1-11-100-1-G-EN Version 11.0, Seite/Page 1 von/of 5, Gültig ab/Valid since 2022-10-20 GRA,hermdede

## 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 with PLASMAPORE® or PLASMAPORE®µ-CaP-coated stems</li> <li>■ for implantation with bone cement, for uncoated stems</li> </ul> <p>The implant range consists of BiCONTACT® S, H, SD, E, EH.</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>4039239000002300ZR</b>

<b>Artikelnummer</b> <i>Ref. Number</i>	<b>Bezeichnung</b> <i>Description</i>	<b>Risikoklasse</b> <i>Risk Class</i>
NJ609T	BICONTACT E PLASMAPORE-µCAP 8/10 SIZE 9	III
NJ610T	BICONTACT E PLASMAPORE-µCAP 8/10 SIZE 10	III
NJ611T	BICONTACT E PLASMAPORE-µCAP 8/10 SIZE 11	III
NJ612T	BICONTACT E PLASMAPORE-µCAP 8/10 SIZE 12	III
NJ613T	BICONTACT E PLASMAPORE-µCAP 8/10 SIZE 13	III
NJ614T	BICONTACT E PLASMAPORE-µCAP 8/10 SIZE 14	III
NJ615T	BICONTACT E PLASMAPORE-µCAP 8/10 SIZE 15	III
NJ616T	BICONTACT E PLASMAPORE-µCAP 8/10 SIZE 16	III
NJ617T	BICONTACT E PLASMAPORE-µCAP 8/10 SIZE 17	III
NJ618T	BICONTACT E PLASMAPORE-µCAP 8/10 SIZE 18	III
NJ619T	BICONTACT E PLASMAPORE-µCAP 8/10 SIZE 19	III
NJ620T	BICONTACT E PLASMAPORE-µCAP 8/10 SIZE 20	III
NJ628T	BICONTACT E PLASMAPORE-µCAP 8/10 SZ.8H	III
NJ629T	BICONTACT E PLASMAPORE-µCAP 8/10 SZ.9H	III
NJ630T	BICONTACT E PLASMAPORE-µCAP 8/10 SZ.10H	III
NJ631T	BICONTACT E PLASMAPORE-µCAP 8/10 SZ.11H	III
NJ632T	BICONTACT E PLASMAPORE-µCAP 8/10 SZ.12H	III
NJ633T	BICONTACT E PLASMAPORE-µCAP 8/10 SZ.13H	III
NJ634T	BICONTACT E PLASMAPORE-µCAP 8/10 SZ.14H	III
NJ635T	BICONTACT E PLASMAPORE-µCAP 8/10 SZ.15H	III
NJ636T	BICONTACT E PLASMAPORE-µCAP 8/10 SZ.16H	III
NJ637T	BICONTACT E PLASMAPORE-µCAP 8/10 SZ.17H	III
NJ638T	BICONTACT E PLASMAPORE-µCAP 8/10 SZ.18H	III

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NJ639T	BICONTACT E PLASMAPORE-μCAP 8/10 SZ.19H	III
NJ640T	BICONTACT E PLASMAPORE-μCAP 8/10 SZ.20H	III

<b>Zweckbestimmung Intended Use</b>	<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 with PLASMAPORE® or PLASMAPORE®μ-CaP-coated stems</li> <li>■ for implantation with bone cement, for uncoated stems</li> </ul> <p>The implant range consists of BiCONTACT® S, H, SD, E, EH.</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>4039239000002302ZV</b>

Artikelnummer Ref. Number	Bezeichnung Description	Risikoklasse Risk Class
NK110T	BICONTACT H PLASMAPORE 12/14 SIZE 10MM	III
NK111T	BICONTACT H PLASMAPORE 12/14 SIZE 11MM	III
NK112T	BICONTACT H PLASMAPORE 12/14 SIZE 12MM	III
NK113T	BICONTACT H PLASMAPORE 12/14 SIZE 13MM	III
NK114T	BICONTACT H PLASMAPORE 12/14 SIZE 14MM	III
NK115T	BICONTACT H PLASMAPORE 12/14 SIZE 15MM	III
NK116T	BICONTACT H PLASMAPORE 12/14 SIZE 16MM	III
NK117T	BICONTACT H PLASMAPORE 12/14 SIZE 17MM	III
NK118T	BICONTACT H PLASMAPORE 12/14 SIZE 18MM	III
NK119T	BICONTACT H PLASMAPORE 12/14 SIZE 19MM	III
NK121T	BICONTACT H PLASMAPORE 12/14 SIZE 21MM	III
NK508T	BICONTACT S PLASMAPORE 12/14 SIZE 8MM	III
NK509T	BICONTACT S PLASMAPORE 12/14 SIZE 9MM	III
NK510T	BICONTACT S PLASMAPORE 12/14 SIZE 10MM	III
NK511T	BICONTACT S PLASMAPORE 12/14 SIZE 11MM	III
NK512T	BICONTACT S PLASMAPORE 12/14 SIZE 12MM	III
NK513T	BICONTACT S PLASMAPORE 12/14 SIZE 13MM	III

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NK514T	BICONTACT S PLASMAPORE 12/14 SIZE 14MM	III
NK515T	BICONTACT S PLASMAPORE 12/14 SIZE 15MM	III
NK516T	BICONTACT S PLASMAPORE 12/14 SIZE 16MM	III
NK517T	BICONTACT S PLASMAPORE 12/14 SIZE 17MM	III
NK518T	BICONTACT S PLASMAPORE 12/14 SIZE 18MM	III
NK519T	BICONTACT S PLASMAPORE 12/14 SIZE 19MM	III
NK520T	BICONTACT S PLASMAPORE 12/14 SIZE 20MM	III
NK521T	BICONTACT S PLASMAPORE 12/14 SIZE 21MM	III
NK709T	BICONTACT SD PLASMAPORE 12/14 SIZE 9MM	III
NK710T	BICONTACT SD PLASMAPORE 12/14 SIZE 10MM	III
NK711T	BICONTACT SD PLASMAPORE 12/14 SIZE 11MM	III
NK712T	BICONTACT SD PLASMAPORE 12/14 SIZE 12MM	III
NK713T	BICONTACT SD PLASMAPORE 12/14 SIZE 13MM	III
NK714T	BICONTACT SD PLASMAPORE 12/14 SIZE 14MM	III
NK715T	BICONTACT SD PLASMAPORE 12/14 SIZE 15MM	III
NK716T	BICONTACT SD PLASMAPORE 12/14 SIZE 16MM	III

<b>Zweckbestimmung Intended Use</b>	<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 with PLASMAPORE® or PLASMAPORE®μ-CaP-coated stems</li> <li>■ for implantation with bone cement, for uncoated stems</li> </ul> <p>The implant range consists of BiCONTACT® S, H, SD, E, EH.</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>403923900000230322</b>

<b>Artikelnummer Ref. Number</b>	<b>Bezeichnung Description</b>	<b>Risikoklasse Risk Class</b>
NK312K	BICONTACT H COCR CEMENTED 12/14 SZ.12MM	III
NK314K	BICONTACT H COCR CEMENTED 12/14 SZ.14MM	III
NK316K	BICONTACT H COCR CEMENTED 12/14 SZ.16MM	III
NK318K	BICONTACT H COCR CEMENTED 12/14 SZ.18MM	III

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NK610K	BICONTACT S COCR CEMENTED 12/14 SZ.10MM	III
NK612K	BICONTACT S COCR CEMENTED 12/14 SZ.12MM	III
NK614K	BICONTACT S COCR CEMENTED 12/14 SZ.14MM	III
NK616K	BICONTACT S COCR CEMENTED 12/14 SZ.16MM	III
NK618K	BICONTACT S COCR CEMENTED 12/14 SZ.18MM	III

<b>Zweckbestimmung</b> <i>Intended Use</i>	<p>The implant is used as a component of a human hip endoprosthesis compatible with the BICONTACT SD and PLASMACUP SC implant and instrument system.</p> <p>Implant components:</p> <ul style="list-style-type: none"> <li>■ SDC = BICONTACT® SD compatible hip stem, cementless</li> <li>■ SDC modular heads, 28 mm in different neck length</li> <li>■ PLC = PLASMACUP® SC compatible pressfit cup, cementless</li> <li>■ The SDC stem and head implant components are packed individually; each has an individual reference number.</li> <li>■ The PLC pressfit-cup is packed together with an 28 mm posterior wall polyethylene insert and 6.5 mm titanium fixation screws</li> <li>■ Combinations of implants of the SDC and PLC series with Aesculap hip endoprosthesis components only</li> </ul> <p>Note</p> <p>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.</p>
<b>Basic-UDI-DI:</b>	<b>403923900000230424</b>

<b>Artikelnummer</b> <i>Ref. Number</i>	<b>Bezeichnung</b> <i>Description</i>	<b>Risikoklasse</b> <i>Risk Class</i>
NK700T	SDC HIP PROSTH.CEMENTLESS 12/14 SZ.10MM	III
NK701T	SDC HIP PROSTH.CEMENTLESS 12/14 SZ.11MM	III
NK702T	SDC HIP PROSTH.CEMENTLESS 12/14 SZ.12MM	III
NK703T	SDC HIP PROSTH.CEMENTLESS 12/14 SZ.13MM	III
NK704T	SDC HIP PROSTH.CEMENTLESS 12/14 SZ.14MM	III
NK705T	SDC HIP PROSTH.CEMENTLESS 12/14 SZ.15MM	III

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