

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 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 IX, Chapter I and III.*

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

Die **Gültigkeit** der Konformitätserklärung entspricht der Geltungsdauer des folgenden Zertifikats:/
Validity of the Declaration of Conformity corresponds to the following certificate:
EU Quality Management System Certificate – Regulation (EU) 2017/745 on medical devices, Annex IX
Chapter I; No. 7400GB448220414; Valid until: 2025-11-15

i.V.

i.V.

Markus Siller
Vice President R&D Orthopaedic & Spine Surgery

Dr. Ina Wüstefeld
Vice President Regulatory & Medical Scientific Affairs

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Zweckbestimmung <i>Intended Use</i>	<p>The implant is used:</p> <ul style="list-style-type: none"> ■ as a component of a human hip endoprosthesis: augmentation implant for filling of acetabular bone defects ■ in combination with Aesculap hip endoprosthesis components: Plasmafit, Plasmafit Revision, Plasmacup, cemented PE cups ■ in combination with implant components explicitly approved by Aesculap ■ in combination with hip endoprosthesis cups with the same nominal diameter, or one that is a maximum of 4 mm smaller/larger ■ in combination with bone cement at the interface to the hip cup <p>The anchoring screws must only ever be used as follows:</p> <ul style="list-style-type: none"> ■ In compliance with the instructions for use of the individual implant components ■ In the stated implant systems according to their color coding <table border="1" data-bbox="467 947 1393 1205"> <tr> <th>Color coding of anchoring screws</th><th>Permitted use of the fixation of the following products</th></tr> <tr> <td>Yellow oxide layer</td><td>Plasmacup</td></tr> <tr> <td>Blue oxide layer</td><td>Plasmafit Plus, Plasmafit Revision Structan acetabulum augmentation implant</td></tr> <tr> <td>Pink oxide layer</td><td>Structan acetabulum augmentation implant</td></tr> </table> <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>	Color coding of anchoring screws	Permitted use of the fixation of the following products	Yellow oxide layer	Plasmacup	Blue oxide layer	Plasmafit Plus, Plasmafit Revision Structan acetabulum augmentation implant	Pink oxide layer	Structan acetabulum augmentation implant
Color coding of anchoring screws	Permitted use of the fixation of the following products								
Yellow oxide layer	Plasmacup								
Blue oxide layer	Plasmafit Plus, Plasmafit Revision Structan acetabulum augmentation implant								
Pink oxide layer	Structan acetabulum augmentation implant								
Basic-UDI-DI:	40392390000025342P								

Artikelnummer <i>Ref. Number</i>	Bezeichnung <i>Description</i>	Risikoklasse <i>Risk Class</i>
NH573T	STRUCTAN ACETABULUM AUGMENT SIZE 48/12MM	IIb
NH574T	STRUCTAN ACETABULUM AUGMENT SIZE 52/12MM	IIb
NH575T	STRUCTAN ACETABULUM AUGMENT SIZE 56/12MM	IIb
NH576T	STRUCTAN ACETABULUM AUGMENT SIZE 60/12MM	IIb
NH577T	STRUCTAN ACETABULUM AUGMENT SIZE 64/12MM	IIb
NH578T	STRUCTAN ACETABULUM AUGMENT SIZE 68/12MM	IIb
NH583T	STRUCTAN ACETABULUM AUGMENT SIZE 48/16MM	IIb
NH584T	STRUCTAN ACETABULUM AUGMENT SIZE 52/16MM	IIb

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NH585T	STRUCTAN ACETABULUM AUGMENT SIZE 56/16MM	IIb
NH586T	STRUCTAN ACETABULUM AUGMENT SIZE 60/16MM	IIb
NH587T	STRUCTAN ACETABULUM AUGMENT SIZE 64/16MM	IIb
NH588T	STRUCTAN ACETABULUM AUGMENT SIZE 68/16MM	IIb
NH593T	STRUCTAN ACETABULUM AUGMENT SIZE 48/20MM	IIb
NH594T	STRUCTAN ACETABULUM AUGMENT SIZE 52/20MM	IIb
NH595T	STRUCTAN ACETABULUM AUGMENT SIZE 56/20MM	IIb
NH596T	STRUCTAN ACETABULUM AUGMENT SIZE 60/20MM	IIb
NH597T	STRUCTAN ACETABULUM AUGMENT SIZE 64/20MM	IIb
NH598T	STRUCTAN ACETABULUM AUGMENT SIZE 68/20MM	IIb
NH603T	STRUCTAN ACETABULUM AUGMENT SIZE 48/25MM	IIb
NH604T	STRUCTAN ACETABULUM AUGMENT SIZE 52/25MM	IIb
NH605T	STRUCTAN ACETABULUM AUGMENT SIZE 56/25MM	IIb
NH606T	STRUCTAN ACETABULUM AUGMENT SIZE 60/25MM	IIb
NH607T	STRUCTAN ACETABULUM AUGMENT SIZE 64/25MM	IIb
NH608T	STRUCTAN ACETABULUM AUGMENT SIZE 68/25MM	IIb
NH613T	STRUCTAN ACETABULUM AUGMENT SIZE 48/30MM	IIb
NH614T	STRUCTAN ACETABULUM AUGMENT SIZE 52/30MM	IIb
NH615T	STRUCTAN ACETABULUM AUGMENT SIZE 56/30MM	IIb
NH616T	STRUCTAN ACETABULUM AUGMENT SIZE 60/30MM	IIb
NH617T	STRUCTAN ACETABULUM AUGMENT SIZE 64/30MM	IIb
NH618T	STRUCTAN ACETABULUM AUGMENT SIZE 68/30MM	IIb

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Zweckbestimmung <i>Intended Use</i>	<p>The 4.5 mm anchoring screw is used in combination with Aesculap acetabular implants.</p> <p>It is used to secure the Structan® acetabulum augmentation implant in the bone.</p> <p>The 4.5 mm anchoring screw may only be used as follows:</p> <ul style="list-style-type: none"> ■ in combination with Aesculap hip endoprosthesis components ■ in combination with implant components explicitly approved by Aesculap ■ in compliance with the instructions for use of the individual implant components ■ in the listed implant systems according to their color coding <table border="1" data-bbox="467 737 1393 814"> <tr> <th>Color coding of anchoring screws</th><th>Permissible use</th></tr> <tr> <td>Pink oxide layer</td><td>Structan® Acetabular Augment</td></tr> </table> <p>The anchoring screw is available in different lengths.</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>	Color coding of anchoring screws	Permissible use	Pink oxide layer	Structan® Acetabular Augment
Color coding of anchoring screws	Permissible use				
Pink oxide layer	Structan® Acetabular Augment				
Basic-UDI-DI:	40392390000025332M				

Artikelnummer <i>Ref. Number</i>	Bezeichnung <i>Description</i>	Risikoklasse <i>Risk Class</i>
NV980T	FIXATION SCREW 4,5X16MM SW3,5	IIb
NV981T	FIXATION SCREW 4,5X20MM SW3,5	IIb
NV982T	FIXATION SCREW 4,5X24MM SW3,5	IIb
NV983T	FIXATION SCREW 4,5X28MM SW3,5	IIb
NV984T	FIXATION SCREW 4,5X32MM SW3,5	IIb
NV985T	FIXATION SCREW 4,5X36MM SW3,5	IIb
NV986T	FIXATION SCREW 4,5X40MM SW3,5	IIb
NV987T	FIXATION SCREW 4,5X44MM SW3,5	IIb
NV988T	FIXATION SCREW 4,5X48MM SW3,5	IIb
NV989T	FIXATION SCREW 4,5X52MM SW3,5	IIb
NV990T	FIXATION SCREW 4,5X56MM SW3,5	IIb
NV991T	FIXATION SCREW 4,5X60MM SW3,5	IIb
NV992T	FIXATION SCREW 4,5X64MM SW3,5	IIb
NV993T	FIXATION SCREW 4,5X68MM SW3,5	IIb

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Title: Plasmefit Rev Structan Implants_DoC_Class IIb.docx Initiator: Sabine ? Nassal

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