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EU Quality Management System 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 introduced, applies and maintains a quality management system for the medical devices/groups of medical devices listed in the appendix.

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

Annex IX Chapter I

Any applicable limitations of this certification for certain medical devices are included in the appendix. This certification is subject to surveillance by MEDCERT.

Effective date:	**2022-04-14**
Expiry date:	**2025-11-15**
Final assessment report No.:	7400PS07F
Procedure No.:	QS – 7400
Certificate No.:	7400GB448220414
Preceding certificate No.:	7400GB448220107
Preceding certificate date:	2022-01-07
Identification of changes:	WO-007935, WO-009638

Hamburg, 2022-04-14

MEDCERT Certification Body
(Lorenz Runge)

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Class I medical devices

For class I medical devices that are reusable surgical instruments (class Ir), the audit of the quality management system was limited to the aspects relating to the reuse of the device, in particular cleaning, disinfection, sterilisation, maintenance and functional testing, and the related instructions for use.

Category	Medical devices/groups of medical devices	Class
MDN 1208	Non-active non-implantable instruments	Ir

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Class IIa medical devices

Category	EMDN code	Medical devices/groups of medical devices
MDA 0202	**Z120111**	Instruments for operative microscopy
MDN 1208	**L0312**	Surgical trocar, reusable
	L070702	Cardiac dilators and retractors, reusable
	L091099	Osteosynthesis instruments, reusable - other
	L091102	Orthopaedic prostheses reamers and burs, reusable
	L091199	Orthopaedic prosthetics instruments, reusable - other
	L110501	Vertebral surgery spreaders and retractors, reusable
	P091203	Bone fixation wires
	P091303	Orthopaedic implant drill bits, single-use
	P091399	Orthopaedic implant instruments, single-use - other
	V0199	Cutting devices, single-use - other
	Z120114	Surgical navigation instruments
	Z121305	Motorised orthopaedic surgery system instruments
	Z120190	Various instruments for general and multidisciplinary surgery
	Z1202	Endoscopic and minimally invasive surgery instruments
	Z120209	Neuroendoscopy instruments

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Class IIb medical devices

Category	EMDN code	Medical devices/groups of medical devices
MDN 1102	**P090701**	Spinal fusion systems Intended purpose: – TA012095: PEEK Cages are used as follows: ■ CeSPACE® PEEK: stabilization of the cervical spine C2-T1 through anterior approach, monosegmental and multisegmental ■ PROSPACE® PEEK: stabilization of the lumbar and thoracic spine through posterior approach, monosegmental and multisegmental ■ TSPACE® PEEK: stabilization of the lumbar and thoracic spine through transforaminal approach, monosegmental and multisegmental. – TA012353: Titanium cages are used as follows: ■ CeSPACE® Ti: stabilization of the cervical spine C2-T1 through anterior approach, monosegmental and multisegmental ■ PROSPACE® Ti PLIF: stabilization of the lumbar and thoracic spine through posterior approach, monosegmental and multisegmental ■ PROSPACE® Ti TLIF: stabilization of the lumbar and thoracic spine through transforaminal approach, monosegmental and multisegmental ■ TSPACE® Ti: stabilization of the lumbar and thoracic spine through transforaminal approach, monosegmental and multisegmental. – TA013625: PLASMAPORE XP® Cages are used as follows: ■ CeSPACE® XP: stabilization of the cervical spine C2-T1 through anterior approach, monosegmental and multisegmental ■ PROSPACE® XP: stabilization of the lumbar and thoracic spine through posterior approach, monosegmental and multisegmental. ■ TSPACE® XP: stabilization of the lumbar and thoracic spine through transforaminal approach, monosegmental and multisegmental. – TA015914: 3D Cages are used as follows: ■ CeSPACE® 3D: stabilization of the cervical spine C2-T1 through anterior approach, monosegmental and multisegmental. ■ PROSPACE® 3D: stabilization of the lumbar and thoracic spine through posterior approach, monosegmental and multisegmental. ■ PROSPACE® 3D Oblique: stabilization of the lumbar and thoracic spine through transforaminal approach, monosegmental and multisegmental. ■ TSPACE® 3D: stabilization of the lumbar and thoracic spine through transforaminal approach, monosegmental and multisegmental.
MDN 1102	**P090703**	Implantable vertebral stabilisation or fixation systems Intended purpose: – TA014887: The Ennovate Spinal System implants are used for dorsal monosegmental and multisegmental stabilization of the lumbar, thoracic and sacral spine. – TA015777: The Ennovate Cervical Spinal System implants are used for the posterior monosegmental and multisegmental stabilization of the occipitocervical junction and of the cervical and upper thoracic spine. The system consists of: Occiput plates and screws, Rods, Polyaxial screws, Bone screws, Set screws, Hook, Cross connectors (head-to-head cross connectors, rod-to-rod cross connectors), Other connectors, Laminoplasty plate. The Ennovate Cervical laminoplasty plate is intended for use in the cervical spine (C3-C6) after a unilateral laminoplasty has been performed. It is fixated to the lamina with the SecureSpan screws. Surgically installed implants serve to support the normal healing process. They are not supposed to replace normal body structures or to support permanent loads that occur in cases where healing does not occur. The laminoplasty plate should be used with a stabilization block (by e.g. a bone graft). Appropriate implant components from Ennovate Spinal System (e.g. rods) can also be used. Special instruments must be used for implanting these components, as well as for the distraction, compression and reduction of the thoracolumbar spine. – TA011187: The S4 Spinal System Implants are used for dorsal monosegmental and multisegmental stabilization of the lumbar and thoracic spine. They comprise: ■ Mono/polyaxial screws ■ Rods ■ Hook ■ Cross connector ■ Rod connectors – parallel, axial and lateral offset ■ appropriate fixation elements. Special instruments must be used for implanting these components, as well as for the distraction, compression and reduction of the lumbar and thoracic spine. – TA012865: The S4 Spinal System implants are used for dorsal monosegmental and multisegmental stabilization of the lumbar and thoracic spine. The S4 Spinal System – augmentation screw can be fixed with bone cement to increase anchoring stability. In this case, the injection cannula is inserted in the S4 Spinal System – augmentation screw for application of the bone cement. The S4 Spinal System - augmentation screw comprises: ■ S4 Monoaxial/polyaxial screws (augmentation screw), supplied in sterile condition ■ S4 Element monoaxial/polyaxial screws (augmentation screw), supplied in sterile condition ■ Cement injection cannula (sterile), see TA013132 ■ for percutaneous application with S4 Element monoaxial/polyaxial screws (augmentation screws): S4 Element Augmentation instruments, see TA014315. Note: There are special S4 instruments provided for the implantation of these system components and for the augmentation, distraction, compression, and reduction of the lumbar and thoracic spine.

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Category	EMDN code	Medical devices/groups of medical devices
MDN 1102	**P090703**	Implantable vertebral stabilisation or fixation systems Intended purpose: – TA013579: Note: The S4 Spinal System – in sterile condition is addressed in general in the operating instructions for the S4 Spinal System – Lumbar/Deformity TA011187. This information on the sterile-packaged S4 implants supplements the respective information in the instructions for use of the S4 Spinal System – Lumbar/Deformity. The S4 Spinal System implants are used for dorsal monosegmental and multisegmental stabilization of the lumbar and thoracic spine. The parallel (closed and open) and axial rod connectors are connected to S4 Spinal System rods in order to connect a rod parallel or in a line with another rod. The lateral offset connectors are connected to the S4 Spinal System rods in order to place a screw offset. The rod connectors thus extend the rod to the adjacent spinal column segments. The S4 Spinal System – sterile-packaged comprises: ■ Rod connector – parallel (closed and open), axial and lateral offset connectors. Note: Special S4 instruments must be used for implanting these components, as well as for the distraction, compression and reduction of the lumbar and thoracic spine. – TA015555: The ArcadiusXP L Interbody Fusion System is a stand alone device intended to be used with four bone screws if no supplement fixation is used to stabilize the lumbar spine through an anterior approach. The system contains: ■ Cages in different heights, angles and footprints ■ Bone screws in different lengths.
MDN 1102	**P090803**	Hip prostheses acetabular components Intended purpose: – TA009880: The implant is used ■ as a component of a human hip endoprosthesis: Hip endoprosthesis cup, consisting of outer cup Plasmafit® Poly or Plasmafit® Plus, possibly central screw plug, possibly anchoring screws and modular Plasmafit® inserts (standard, asymmetrical or with shoulder) ■ in combination with Aesculap hip endoprosthesis components ■ in combination with implant components explicitly approved by Aesculap ■ for implantation without bone cement. Note. The options of 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.
MDN 1102	**P090880**	Hip prostheses – accessories Intended purpose: – TA009897: The anchoring screws are used in combination with Aesculap acetabular implants. They are used to increase stability in the event of insufficient primary stability in Plasmacup® and Plasmafit® press fit cups and to secure the Aesculap reconstruction cup and the acetabular Structan® Augment in the bone. The 6.5 mm anchoring screws may only be used as explained below: ■ 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. Color coding of anchoring screws / Permissible use - Yellow oxide layer Plasmacup® and Aesculap recon ring - Blue oxide layer Plasmafit® and acetabular Structan® Augment. Anchoring screws are available in different lengths. Note: The options of 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. – TA012526: The implant is used: ■ as a component part of a human hip endoprosthesis: Locking screw ■ in combination with Aesculap hip endoprosthesis stems with locking holes ■ in combination with implant components explicitly approved by Aesculap ■ in compliance with the instructions for use of the individual implant components. The locking screws are intended for the fixation of above-mentioned implant components that allow distal locking. The operating surgeon decides, depending on the indication, if and to what degree implant locking is necessary.

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Category	EMDN code	Medical devices/groups of medical devices
MDN 1102	**P090880**	Hip prostheses – accessories Intended purpose: – TA008056: The Centralizer is used as an additional guide when using cemented Aesculap endoprosthesis stems. It acts as a guide for the distal tip of the prosthesis when inserting the stem into the bone cement. If the correct size has been selected, the Centralizer guarantees a closed and uniform cement socket. Different outer diameters are available for centralizers; they are marked on the packaging. The selection of the correct centralizer depends on the Aesculap hip implant stem used or the Aesculap knee implant component used, and the operative preparation and size of the medullary cavity. Observe the instructions for use for the Aesculap endoprosthesis components used. The Centralizer is used with Aesculap Endoprosthesis Centrament, Bicontact, Excia, SLA, Vega and Columbus. – TA012315: For use with a cemented Trilliance or CoreHip hip endoprosthesis stem. See instructions for use of Trilliance-/CoreHip hip endoprosthesis stems. – TA013723: The implant is used: ■ 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 Revison, Plasmacup, cemented PE cups ■ in combination with implant components explicitly approved by Aesculap ■ in combination with hip endoprosthesis cups with the sam e 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. The anchoring screws must only ever be used as follows: ■ In compliance with the instructions for use of the individual implant components ■ In the stated implant systems according to their color coding. Yellow oxide layer - Plasmacup; Blue oxide layer - Plasmafit Plus, Plasmafit Revision, Structan acetabulum augmentation implant; Pink oxide layer - Structan acetabulum augmentation implant. 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. – TA015599: The 4.5 mm anchoring screws are used in conjunction with Aesculap acetabulum implants. It serves to secure the Structan® acetabulum augmentation in the bone. The 4.5 mm anchoring screws may only be used as follows: ■ In compliance with the instructions for use of the individual implant components ■ In the stated implant systems according to their color coding. Pink oxide layer - Structan® acetabulum augmentation. The anchoring screws are available in various lengths.
MDN 1102	**P090908**	Knee prostheses spacers Intended purpose: – TA016100: The implant is used: ■ as a component of a human knee endoprosthesis that consists of a femoral, tibial and meniscal implant component and possibly patella, extension stems and augment implants ■ in combination with implant components explicitly approved by Aesculap – univation® X, – Columbus®, – e.motion®, – VEGA System®, – EnduRo ■ for implantation without bone cement with PLASMAPORE® or PLASMAPORE® µ-CaP coated implants and cementless extension stems ■ for implantation with bone cement for other knee implants including All-poly tibia implants except meniscal components. 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.
MDN 1102	**P090980**	Knee prostheses - accessories Intended purpose: – TA016100: The implant is used: ■ as a component of a human knee endoprosthesis that consists of a femoral, tibial and meniscal implant component and possibly patella, extension stems and augment implants ■ in combination with implant components explicitly approved by Aesculap – univation® X, – Columbus®, – e.motion®, – VEGA System®, – EnduRo ■ for implantation without bone cement with PLASMAPORE® or PLASMAPORE® µ-CaP coated implants and cementless extension stems ■ for implantation with bone cement for other knee implants including All-poly tibia implants except meniscal components. 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.

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Class III custom-made implantable medical devices

Category	Medical devices/groups of medical devices
MDN 1102	Non-active osteo- and orthopaedic implants

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Class III medical devices

For placing on the market of class III medical devices covered by this certificate, an additional EU Technical Documentation Assessment Certificate according to Annex IX Chapter II of Regulation (EU) 2017/745 is required, which also contains the exact determination of medical devices covered by certification.

Category	Medical devices/groups of medical devices
MDA 0312	Other active non-implantable surgical devices
MDN 1101	Non-active cardiovascular, vascular and neurovascular implants
MDN 1102	Non-active osteo- and orthopaedic implants
MDN 1202	Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis
MDN 1208	Non-active non-implantable instruments

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