



EC Certificate
Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60148793 0001

Report No.: 21227915 032

Manufacturer: Königsee Implantate GmbH
Am Sand 4
07426 Allendorf
Deutschland

Products: Non-active orthopaedic implants
Non-active orthopaedic instruments

(see attachment for products included)

Replaces Certificate, Registration No.: HD 60097612 0001

Expiry Date: 2024-05-26

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2020-04-23

Notified Body

Date: 2020-04-17

Dr.



TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.



EC Certificate
Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60144470 0001

Report No.: 26300276 011

Manufacturer: MEDGAL Sp. z o.o.
ul. Niewodnicka 26 A
16-001 Ksiezyno
Poland

Products: (see attachment for products included)

Replaces EC Certificate, Registration No.: HD 60113494 0001

Expiry Date: 2024-05-26

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2019-12-20

Date: 2019-12-20

Notified Body



TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 1/2, Rev. 0

**Attachment to
Certificate**

Registration No.: HD 60144470 0001
Report No.: 26300276 011

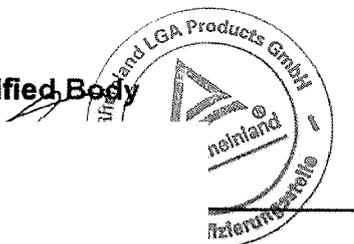
Manufacturer: MEDGAL Sp. z o.o.
ul. Niewodnicka 26 A
16-001 Ksiezyno
Poland

Products included:

- Non-sterile and sterile bone nails
- Non-sterile bone nails DLC coated
- Non-sterile bone nails Si-DLC coated
- Non-sterile and sterile fixation device, internal, wires
- Non-sterile fixation device, internal, wires DLC coated
- Non-sterile and sterile bone pins
- Non-sterile fixation device, internal, wires Si-DLC coated
- Non-sterile bone pins DLC coated
- Non-sterile bone pins Si-DLC coated
- Non-sterile and sterile bone staples
- Non-sterile bone staples DLC coated
- Non-sterile and sterile bone screws
- Non-sterile bone staples Si-DLC coated
- Non-sterile bone screws DLC coated
- Non-sterile bone screws Si-DLC coated

Date: 2019-12-20

Notified Body



**TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg**

Doc. 2/2, Rev. 0

**Attachment to
Certificate**

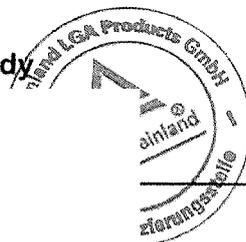
Registration No.: HD 60144470 0001
Report No.: 26300276 011

Manufacturer: MEDGAL Sp. z o.o.
ul. Niewodnicka 26 A
16-001 Ksiezyno
Poland

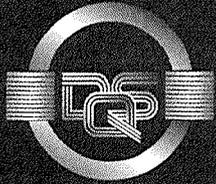
Products included:

- Non-sterile and sterile fixation device, internal, washers
- Non-sterile fixation device, internal, washers DLC coated
- Non-sterile fixation device, internal, washers Si-DLC coated
- Non-sterile and sterile bone plates
- Non-sterile bone plates DLC coated
- Non-sterile bone plates Si-DLC coated
- Non-sterile and sterile fixation device, internal, hip, plate, compression
- Non-sterile fixation device, internal, hip, plate, compression DLC coated
- Non-sterile fixation device, internal, hip, plate, compression Si- DLC coated
- Non-sterile and sterile fixation device, maxillofacial plates
- Non-sterile and sterile modular hemi hip joint prostheses
- Non-sterile orthopaedic surgical instruments connected to active medical devices

Notified Body



Date: 2019-12-20



EC-CERTIFICATE

(Full quality assurance system)

This is to certify that the company

Auxein Medical Pvt Ltd

PlotNo.168,169,
170 Phase-IV, Sector 57, Kundli Industrialarea,
HSIIDC Sonapat- 131028 Haryana
India

has implemented and maintains a full quality assurance system which applies to the products at every stage from design to final controls.

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of

Annex II – excluding Section 4 of Council Directive 93/42/EEC concerning medical devices

with respect to the following medical devices:

Nail Systems- non sterile and Bone Screw & Plate Systems - non sterile according to annex

The manufacturer is subject to surveillance according to Annex II, Section 5. The CE marking with the Notified Body Identification Number (0297) may be affixed on the devices listed in the certificate. An EC Design Examination Certificate according to Annex II, Section 4 is required for class III devices covered by this certificate. The certificate is in the case of class I(s) devices (I(s) = class I products placed on the market in sterile conditions) limited to the aspects of manufacture concerned with securing and maintaining sterile conditions. The certificate is in the case of class I(m) devices (I(m) = class I devices with a measuring function) limited to the aspects of manufacture concerned with the conformity of the products with the metrological requirements.

Certificate registration no.	543473 MR2
Certificate unique ID	170753735
Effective date	2020-05-11
Expiry date	2024-05-26
Frankfurt am Main	2020-05-11

DQS Medizinprodukte GmbH

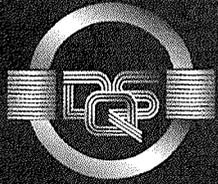
Managing Director

Head of Certification Body

August-Schanz-Straße 21, 60433 Frankfurt am Main,
Tel. +49 (0) 69 95427-300, medical.devices@dqs-med.de

DQS Medizinprodukte GmbH is a Notified Body according to Council Directive 93/42/EEC concerning medical devices with the Identification Number 0297.





Annex to certificate

Certificate registration No.: 543473 MR2

Certificate unique ID: 170753735

Effective date: 2020-05-11

Auxein Medical Pvt Ltd

PlotNo.168,169,
170 Phase-IV, Sector 57, Kundli Industrialarea,
HSIIDC Sonapat- 131028 Haryana
India

105
15



Device Family	Device	GMDN Codes	Class
Nail Systems	PFNA nailing system	63875 47875 56643	IIb
	Femur Nailing system	63875 47875 56643	IIb
	Humerus nailing system	63875 47875 56644	IIb
	Tibia Nailing system	63875 47875 56645	IIb
Bone Screw & Plate Systems	DCP plate system	61574 56642	IIb
	clavicle system	61574 56642	IIb
	DHC-DCS plate system	61574 56642	IIb
	Wrist system	61574 56642	IIb
	Hand and Foot system	61574 56642	IIb
	Cannulated bone screw	56642	IIb
	Small and large fragment system locking	61574 56642	IIb
	Small and large fragment system non locking	61574 56642	IIb



This annex is only valid in connection with the above-mentioned certificate.



EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
(Class IIa and Class IIb Devices)

No. G10 052763 0027 Rev. 00

Manufacturer:

Orthofix S.r.l.

Via delle Nazioni, 9
37012 Bussolengo - VR
ITALY

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s).

The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.

The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.

The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with.

For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:G10 052763 0027 Rev. 00](http://www.tuvsud.com/ps-cert?q=cert:G10_052763_0027_Rev_00)

Report No.: ITA1502855

Valid from: 2021-02-17

Valid until: 2025-11-26

Handwritten signature

Issue date: 2021-02-17

Head of Certification/Notified Body



Benannt durch Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zfa.de
BS-MDR-099



Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
(Class IIa and Class IIb Devices)

No. G10 052763 0027 Rev. 00

Classification: IIb
Device Group: P09120503 - OSTEOSYNTHESIS SCREW-PLATE SYSTEMS
Intended Purpose: Plates intended to provide bone fixation

Classification: IIa
Device Group: Z12139099 - VARIOUS ORTHOPEDIC AND TRAUMATOLOGY INSTRUMENTS - OTHERS
Intended Purpose: /

The validity of this certificate /
depends on conditions and/or
is limited to the following: