



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

Sigrid Uhlemann
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Head of Certification Body

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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
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| 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 |