



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,
HSI IDC 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

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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