

HOSPITAL EQUIPMENT MANUFACTURING COMPANY

HEMC/DoC/IP/01 Rev.00 Dt.: 01-02-2013

DECLARATION OF CONFORMITY



Manufacturer:

Hospital Equipment Manufacturing Co.

Address:

D-313, Sector 63, NOIDA, INDIA



CMC Medical Devices and Drugs S.L., Malaga, Spain

Product: Secure Locking Screws, Plates & Instruments, Interlocking Nails and Instruments, Spine Implants and Instruments, Hip Implants & Instruments, Nails, Wires and Pins, Mini, Small, Large Fragment Implants and Instruments, Cannulated Screws, Maxillo Facial implants and Instruments, Hip Prosthesis, External Fixators.

Conformity Assessment Route:

Annex II (Full Quality Assurance)

We declare that our products as mentioned above, comply to the requirements to Medical device Directive 93/42/EEC

Company undertakes to manufacture the products as per National/ International Standards and following quality management system as per EN ISO 13485:2016

3 . Company authorizes the notified body to carry out necessary inspection and agrees to supply the required information & data/documents from time to time.

4 . Company agrees to make available all relevant Documents & Data of the products to the National Authority for a period ending (Five years) after the last product has been manufactured.

5 . Company or his authorized representative shall fulfil the obligations imposed by Annex II of Medical Device Directive 93/42/EEC & ensures & declares that the Company's Products shall meet all provision of the directive as applicable.

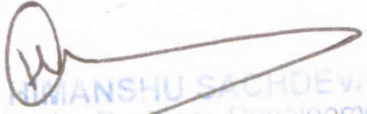
6 . Company undertakes to keep up to date a systematic procedure to review experience gained during post production phase and to implement appropriate means to apply any necessary corrective action taking account of the nature & risk in relation to the product.

7 . Company undertakes to notify immediately any malfunction /deterioration of the performance of the device to the appropriate authority and shall recall such devices already placed in the market

Place, Date of Issue: 27/08/2018

Noida, India

Signature:


ANSHU SACHDEV
Director Business Development
Hospital Equipment MFG Co.
D - 313 Sector - 63
Noida - 201301, Up India





CERTIFICATE

Quality Austria - Trainings, Zertifizierungs und Begutachtungs GmbH awards this **qualityaustria** certificate to the following organisation:

This **qualityaustria** certificate confirms the application and further development of an effective

Hospital Equipment Manufacturing Co.

D-313, Sector-63, Noida UP-201301, INDIA
Sites: A-19 & 20, Sector-7, Noida, Uttar Pradesh, India

QUALITY MANAGEMENT SYSTEM

complying with the requirements of standard

ISO 13485:2016

Medical devices - Quality management systems - Requirements for regulatory purposes

Quality Austria - Trainings, Zertifizierungs und Begutachtungs GmbH is accredited according to the Austrian Accreditation Act by the BMWF/W (Federal Ministry of Science, Research and Economy).

Quality Austria is accredited as an organisation for environmental verification by the BMLFUW (Federal Ministry of Agriculture, Forestry, Environment and Water Management).

Quality Austria is authorized by the VQA (Association of the Automotive Industry).

For accreditation registration details please refer to the applicable decisions or recognition documents.

Quality Austria is the Austrian member of IQNet (International Certification Network).



Doc. Nr. FQ_24_028

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The current validity of the certificate is documented exclusively on the Internet under <http://www.qualityaustria.com/en/cert> EAC: 19.2

Design, Manufacture and Sale of Medical, Laboratory, Scientific & Orthopaedic Implants and Instruments.

Registration No.: 00360/0

Date of initial issue: 22 February 2021


Valid until: 21 February 2024



Vienna, 22 February 2021

Quality Austria - Trainings, Zertifizierungs und Begutachtungs GmbH,
AT-1010 Vienna, Zelinkagasse 10/3


Konrad Scheiber
General Manager


Dr. Mag. Anni Koubek
Specialist representative



