Certificate

Digitally signed by Iarovoi Petru
Date: 2023.03.13 12:16:16 EET
Reason: MoldSign Signature
Location: Moldova

Certificate of Compliance

We hereby declare that the technical file of product class 1 complied with the requirement of the Medical Council Directives 93/42/EEC of June 1993.

Manufacturer

Name : HOSPITAL EQUIPMENT MFG. CO.

Address : MFG. CO.: D-313, SECTOR-63, NOIDA, U.P.-201301, INDIA

Product : As Per Annexures

Complies with the requirements applicable to it

The Certification body has performed an audit of the above product quality system covering the design, manufacture and final inspection of the certified product. The quality system has been assessed, approved and is subject to continuous surveillance according to the directive Medical Council Directive 93/42/EC of June 1993.

This certificate is issued under the following conditions:

1. It applies only to the quality system maintained in the manufacture of above referenced models and it does not substitute the design or type-examination procedures, if requested.
2. The certificate remains valid until the manufacturing conditions or the quality systems are changed.
3. The certificate validity is conditioned by positive results or surveillance audits.
4. After fulfilling the relevant EU legislation, the manufacturer shall affix to each device, of the referenced models.
5. The CE mark as shown above can be used, under the responsibility of the manufacturer, after completion of an EC Declaration of conformity and compliance with all relevant EC Directives. The statement is based on a single evaluation of one sample of above mentioned product. It does not imply an assessment of the whole production

Date of Registration	30 December 2022
1st Surveillance Due	29 December 2023
2nd Surveillance Due	29 December 2024
Recertification Due(subject to the company maintaining system to the required standard)	29 December 2025

Certificate No.: 202301222

Validity of this certificate can be verified at www.qvcert.co.uk

CE

Authorised Signatory

Quality Veritas Certification Limited

Validity of this certificate is subject to annual surveillance audits done successfully

This Certificate Of Registration Remains The Property of Quality Veritas Certification Limited and Shall be Returned Immediately Upon Request

Email:- info@qvcert.co.uk Website:- www.qvcert.co.uk

Suit 48, 88-90 Hatton Garden, London, EC1N 8PN, UK

Certificate

Certificate of Compliance

Certificate of Compliance — Appendix Certificate No. 202301222

Manufacturer: - HOSPITAL EQUIPMENT MFG. CO.
Address: - D-313, SECTOR-63, NOIDA, U.P.-201301, INDIA

This certificate referred to above covers the following products:

	Orthopaedic Implants
1	Locking Plates and Screws
2	Small/Medium/Large Fragment Implants
3	Maxillofacial Implants
4	External Fixators
5	Spine Implants
6	Mini Fragment Implants
7	Interlocking Nails
8	Hip Prosthesis
9	Wires and Pins
10	Cannulated screws
	Instruments for Orthopaedic Implants
1	Diamond Pointed Bone Awl
2	Tissue Protector
3	Guide Rod Ø2.5mm
4	Reaming Rod Ø2.5mm
5	Medullary Tube
6	T-Wrench 11mm
7	Cannulated Guide Rod
8	Ram
9	Flexible Grip for Cannulated Guide Rod
10	Proximal Jig for Femoral Nails (Ø9mm to Ø12mm)
11	Proximal Jig for Femoral Nails (Ø13mm to Ø16mm)
12	Proximal Jig for Tibial Nails (Ø8mm to Ø12mm)

CE

Authorised Signatory

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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

EC REP 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.

Confomity Assessmet 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 SACHDEVA
Director Business Development
Hospital Equipment MFG Co.
D - 313 Sector - 63
Noida - 201301 Up (India)

REPUBLICA MOLDOVA, mun. CHIŞINAU • FIRMA DE PRODUCERE ŞI COMERŢ "SOGNO" S.R.L. • IDNO 1014600013854 Sogno S.R.L.

qualityaustria
Succeed with Quality

CERTIFICATE

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

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

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

The validity of the **quality**austria certificate will be maintained by annual surveillance audits and one renewal audit after three years.

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

QUALITY MANAGEMENT SYSTEM
complying with the requirements of standard
ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes

Registration No.: 00360/0
Date of initial issue: 22 February 2021
Valid until: 21 February 2024

qualityaustria

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

Quality Austria - Trainings, Zertifizierungs und Begutachtungs GmbH is accredited according to the Austrian Accreditation Act by the BMWFW (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 VDA (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. FO_24_026

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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

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