Digitally signed by Iarovoi Petru
Date: 2022.08.17 10:20:21 EEST
Reason: MoldSign Signature
Location: Moldova

Otabu

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 : 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 Initial Registration	20th January 2017
Date of Registration	06th January 2020
Ist Surveillance Due	05th January 2021
2nd Surveillance Due	05th January 2022
Certificate expiry	05th January 2023

Certificate No.: 1624

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

OTABU CERTIFICATION LIMITED (UK)

CE

Authorised Signatory

Otabu Certification Limited (UK)

Validity of this Certificate is subject to Annual Surveillance audits done successfully

This Certificate of Registration remains the Property of Otabu Certification Limited and shall be returned immediately upon request.

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

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

Certificate

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Certificate of Compliance

Certificate of Compliance **Appendix Certificate No. 1624**

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

This certificate referred to above covers the following products:

979	Twisted Plates all sizes
980	Post Male and female all sizes
981	Threaded Sockets all sizes
982	Connection plates with threaded End all sizes
983	Wrenchchocubes all sizes
984	Threaded Rod all sizes and dia
985	Threaded Rod , slotted all sizes and dia
986	Combo Screw driver set
987	Cannulated Drill bits all type and sizes
988	Flexible Reaming Shaft withFixed Reamers all sizes
989	Cannulated reamers
990	Plate Bending Press
991	Bone file with fibre handle (Flat & Round)
992	Plaster Shear
993	Bandage Cutting scissors
994	Gigli saw wire
995	Hammer nylon head
996	Bone cutters (Str & Curved)
997	Bone Nibblers (Str & Curved, Angular
998	Bone holding forceps (All types and sizes)
999	Bone Clamp
1000	Bone Scoop
1001	Self retaining retractors (All types and sizes)
1002	Hohmann Retractors all sizes
1003	Screws Drivers all sizes (With or without sleeve)
1004	Carbon Fiber Full Rings (Adult/Child/Pediatric) all sizes
1005	Carbon Fiber3/4 Rings (Adult /Child/Pediatric) all sizes
1006	Carbon Fiber 5/8 Rings (Adult/child/Pediatric) all sizes
1007	Carbon Fiber 1/2 Rings (Adult/Child/Pediatric) all sizes
1008	Carbon Fiber 3/8 Rings (Adult/Child/Pediatric) all sizes

OTABU CERTIFICATION LIMITED (UK)

CE

Authorised Signatory

Otabu Certification Limited (UK)

Validity of this Certificate is subject to Annual Surveillance audits done successfully

This Certificate of Registration remains the Property of Otabu Certification Limited and shall be returned immediately upon request.

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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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