

# Certificate

## 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

20<sup>th</sup> January 2017

Date of Registration

06<sup>th</sup> January 2020

1<sup>st</sup> Surveillance Due

05<sup>th</sup> January 2021

2<sup>nd</sup> Surveillance Due

05<sup>th</sup> January 2022

Certificate expiry

05<sup>th</sup> January 2023

Certificate No.: 1624

Validity of this certificate can be verified at [www.otabucert.co.uk](http://www.otabucert.co.uk)



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](mailto:info@otabucert.co.uk) Website:- [www.otabucert.co.uk](http://www.otabucert.co.uk)

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





## 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 Fiber 3/4 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



*J. Khan*

Authorised Signatory

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