QS

QUALITY SERVICE

CERTIFICATE

Certificate no. 14418

Hospital Equipment Manufacturing Company

D-313, Sector 63, NOIDA-201301,
Uttar Pradesh, India

Digitally signed by Iarovoi Petru
Date: 2019.12.03 15:49:08 EET
Reason: MoldSign Signature
Location: Moldova

QS ZÜRICH AG certifies that the management system of the above mentioned company has been evaluated and meets the requirements established by the following rules:

EN ISO 13485: 2016

The management system includes:

FIRMA DE PRODUCERE ȘI COMERȚ "SOGNO" S.R.L. Sogno S.R.L. IDNO 1004600013854 REPUBLICA MOLDOVA MUN. CHIȘINĂU

Manufacture, Sale and Distribution of Medical, Laboratory, Scientific & Orthopaedic Devices and Instruments.

During the period of validity of this certificate, the management system of the company must always comply with the requirements of the certified standards.

For updated amendments within the scope of certification of the present certificate, please refer to http://www.quality-service.ch/

Audit date:	15.01.2018
Date of issue:	12.02.2018
Expiration date:	11.02.2021
Subject to successful surveillance audit	

QS ZÜRICH AG
P.O. Box 6335
CH-8050 Zürich
info@quality-service.ch

Management

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)

REPREZENTANTA FIRMA DE PRODUCERE ȘI COMERȚ "SOGNO" S.R.L.
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