CERTIFICATE

FULL QUALITY ASSURANCE SYSTEM APPROVAL EC CERTIFICATE

n. 0068/QCO-DM/086-2018

according to Annex II of Directive 93/42/EEC on Medical Devices as amended..

MTIC Intercert hereby declares that an examination of the under mentioned Full Quality Assurance System has been carried out following the requirements of the legislation to which the undersigned is subjected, transposing annex II (with the exemption of section 4) of the Directive 93/42/EEC on Medical Devices. **MTIC Intercert certifies that the Full Quality Assurance System conforms with the relevant provisions of the aforementioned legislation. The validity of this certificate is subjected to the positive result of required surveillance audits.**

MANUFACTURER: **HOSPITAL EQUIPMENT MANUFACTURING COMPANY**

D-313, Sector 63, NOIDA-201301, Uttar Pradesh (INDIA)

DEVICE/S: **Orthopaedic Implants**

MODEL/S: **Spinal systems:**
Plates – Cages – Hooks – Crosslink connectors – Rods - Staples
full list of models in annex 1

Digitally signed by Iarovoi Petru
Date: 2020.02.20 09:41:46 EET
Reason: MoldSign Signature
Location: Moldova

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

FIRST ISSUE: **29/10/2018** CURRENT ISSUE: **29/10/2018** REVISION Nr.: **00** EXPIRING DATE: **28/10/2021**

This certificate is also composed by n. 1 annex of n. 3 pages

Dipl.-Ing. Feridoon Sergizzares
MTIC INTERCERT Certification Body

MTIC® INTERCERT

CERTIFICATE

ANNEX No. 1 TO THE FULL QUALITY ASSURANCE SYSTEM APPROVAL EC CERTIFICATE

n. 0068/QCO-DM/086-2018

according to Annex II of Directive 93/42/EEC on Medical Devices as amended..

SPINAL SYSTEM – PLATES / CAGES / HOOKS / CROSSLINK CONNECTORS / RODS / STAPLES

HTi-469.4525	HTi-469.5525	HTi-469.6525	H479.4025	H479.5050	H479.6050
HTi-469.4530	HTi-469.5530	HTi-469.6530	H479.4030	H479.5055	H479.6055
HTi-469.4535	Ti-469.5535	HTi-469.6535	H479.4035	HTi-479.5030	HTi-479.6030
HTi-469.4540	Ti-469.5540	HTi-469.6540	H479.4040	HTi-479.5035	HTi-479.6035
HTi-469.4545	Ti-469.5545	HTi-469.6545	HTi-479.4020	HTi-479.5040	HTi-479.6040
H489.4020	Ti-469.5550	HTi-469.6550	HTi-479.4025	HTi-479.5045	HTi-479.6045
H489.4025	H489.5030	H489.6030	HTi-479.4030	HTi-479.5050	HTi-479.6050
H489.4030	H489.5035	H489.6035	HTi-479.4035	HTi-479.5055	HTi-479.6055
H489.4035	H489.5040	H489.6040	HTi-479.4040	HTi-456.5525	HTi-456.6525
H489.4040	H489.5045	H489.6045	HTi-456.4525	HTi-456.5530	HTi-456.6530
HTi-489.4020	H489.5050	H489.6050	HTi-456.4530	HTi-456.5535	HTi-456.6535
HTi-489.4025	H489.5055	H489.6055	HTi-456.4535	HTi-456.5540	HTi-456.6540
HTi-489.4030	HTi-489.5030	HTi-489.6030	HTi-456.4540	HTi-456.5545	HTi-456.6545
HTi-489.4035	HTi-489.5035	HTi-489.6035	HTi-456.4545	HTi-456.5550	HTi-456.6550
HTi-489.4040	HTi-489.5040	HTi-489.6040	HTi-459.5540	HTi-459.6540	HTi-459.5550
HTi-459.4525	HTi-489.5045	HTi-489.6045	HTi-459.5545	HTi-459.6545	HTi-459.6550
HTi-459.4530	HTi-489.5050	HTi-489.6050	H479.5030	H479.6030	H479.5035
HTi-459.4535	HTi-489.5055	HTi-489.6055	H479.6035	H479.5040	H479.6040
HTi-459.4540	HTi-459.5525	HTi-459.6525	H479.5045	H479.6045	HTi-459.6535
HTi-459.4545	HTi-459.5530	HTi-459.6530	H479.4020	HTi-459.5535	

FIRMA DE PRODUCERE ŞI COMERŢ "SOGNO" S.R.L. CHIŞINĂU REPUBLICA MOLDOVA IDNO 1004600013854 Sogno S.R.L.

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Dipl.-Ing. Peridoph Sergizzarea
MTIC INTERCERT Certification Body

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www.mticert.org

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n. 0068/QCO-DM/086-2018

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SPINAL SYSTEM – PLATES / CAGES / HOOKS / CROSSLINK CONNECTORS / RODS / STAPLES

H476.5030	HTi-476.5030	HTi-201.426-S	HTi-202.3-100
H476.5035	HTi-476.5035	HTi-201.426-L	HTi-202.55-120
H476.5040	HTi-476.5040	HTi-201.428-S	HTi-202.55-160
H476.5045	HTi-476.5045	HTi-201.428-L	HTi-202.55-180
H476.5050	HTi-476.5050	HTi-201.430-S	HTi-202.55-200
H476.5055	HTi-476.5055	HTi-201.430-L	HTi-202.55-300
H476.6030	HTi-476.6030	HTi-201.432-S	HTi-202.55-480
H476.6035	HTi-476.6035	HTi-201.432-L	HTi-201.411- S
H476.6040	HTi-476.6040	HTi-201.434-S	HTi-201.411- L
H476.6045	HTi-476.6045	HTi-201.434-L	HTi-201.415-S
H476.6050	HTi-476.6050	HTi-202.3-75	HTi-201.415-L
H476.6055	HTi-476.6055	HTi-202.3-80	
HTi- 205.10- 20	HTi- 205.12- 20	HTi- 205.14- 20	HTi- 205.16- 20
HTi- 205.10- 25	HTi- 205.12- 25	HTi- 205.14- 25	HTi- 205.16- 25
HTi- 205.10- 30	HTi- 205.12- 30	HTi- 205.14- 30	HTi- 205.16- 30
HTi- 205.10- 35	HTi- 205.12- 35	HTi- 205.14- 35	HTi- 205.16- 35
HTi- 205.10-40	HTi- 205.12-40	HTi- 205.14-40	HTi- 205.16-40
HTi- 205.10- 45	HTi- 205.12- 45	HTi- 205.14- 45	HTi- 205.16- 45
HTi- 205.10- 50	HTi- 205.12- 50	HTi- 205.14- 50	HTi- 205.16- 50
HTi- 205.18- 20	HTi- 205.20- 20	HTi- 205.22- 20	HTi- 205.24- 20
HTi- 205.18- 25	HTi- 205.20- 25	HTi- 205.22- 25	HTi- 205.24- 25
HTi- 205.18- 30	HTi- 205.20- 30	HTi- 205.22- 30	HTi- 205.24- 30
HTi- 205.18- 35	HTi- 205.20- 35	HTi- 205.22- 35	HTi- 205.24- 35
HTi- 205.18- 40	HTi- 205.20- 40	HTi- 205.22- 40	HTi- 205.24- 40
HTi- 205.18- 45	HTi- 205.20- 45	HTi- 205.22- 45	HTi- 205.24- 45
HTi- 205.18- 50	HTi- 205.20- 50	HTi- 205.22- 50	HTi- 205.24- 50
HTi- 205Ex.12 -20	HTi- 205Ex.14 -20	HTi- 205Ex.16 -20	HTi- 205Ex.18 -20
HTi- 205Ex.12 -25	HTi- 205Ex.14 -25	HTi- 205Ex.16 -25	HTi- 205Ex.18 -25
HTi- 205Ex.12 -35	HTi- 205Ex.14 -35	HTi- 205Ex.16 -35	HTi- 205Ex.18 -35
HTi- 205Ex.12 -55	HTi- 205Ex.14 -55	HTi- 205Ex.16 -55	HTi- 205Ex.18 -55

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

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Dipl.-Ing. Feridoon Sergizzarea
MTIC INTERCERT Certification Body

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HTi-205TF.004	HTi-207.010	HTi-207.021	HTi-207.032
HTi-205TF.011	HTi-207.011	HTi-207.022	HTi-207.033
HTi-207.001	HTi-207.012	HTi-207.023	HTi-208.010
HTi-207.002	HTi-207.013	HTi-207.024	HTi-208.012
HTi-207.003	HTi-207.014	HTi-207.025	HTi-208.014
HTi-207.004	HTi-207.015	HTi-207.026	HTi-208.016
HTi-207.005	HTi-207.016	HTi-207.027	HTi-208.018
HTi-207.006	HTi-207.017	HTi-207.028	HTi-208.020
HTi-207.007	HTi-207.018	HTi-207.029	HTi-208.022
HTi-207.008	HTi-207.019	HTi-207.030	HTi-208.024
HTi-207.009	HTi-207.020	HTi-207.031	HCLS-208-Ti

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

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Dipl.-Ing. Ferdinando Salvatore
MTIC INTERCERT Certification Body

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www.mticert.org

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.
Sogno S.R.L.
IDNO 1014600013854
REPUBLICA MOLDOVA, mun. CHIȘINĂU

QS

QUALITY SERVICE

CERTIFICATE

Certificate no. 14418

Hospital Equipment Manufacturing Company

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

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. REPUBLICA MOLDOVA mun. CHIȘINĂU IDNO 1004600013854 Sogno® S.R.L.

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