



C E R T I F I C A T E

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



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

Dip.-Ing. Periclean Sergizarea
MTIC INTERCERT Certification Body



C E R T I F I C A T E

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

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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	



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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



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[Signature]
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