



C E R T I F I C A T E

FULL QUALITY ASSURANCE SYSTEM APPROVAL EC CERTIFICATE

n. 0068/QCO-DM/085-2018

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: Bone plates
full list of models in annex 1

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This certificate is also composed by n. 1 annex of n. 23 pages


Dipl. Ing. Ferioun Sergizarea
MTIC INTERCERT Certification Body