

## FULL QUALITY ASSURANCE SYSTEM APPROVAL EC CERTIFICATE

n. 0068/QCO-DM/331-2021

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:

SIORA SURGICALS PRIVATE LIMITED

Registered site: WZ-1, 2nd Floor, Phool Bagh, Ram Pura, New Delhi, 1100335, INDIA

Manufacturing site:

1792, HSIIDC Industrial Estate, RAI, District, Sonipat, Haryana, 131029, INDIA

DEVICE/S:

Intramedullary Nail System

MODEL/S:

- Femoral interlocking Nail
- Tibial interlocking Nail
- Locking bolt and helical blade
- End cap for the interlocking nails
- **Tibial nail instruments**
- Adroit Multifix Tibia Nail Instruments

list of each model covered by this certificate is available by the NB

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27/05/2024





Dipl.- Ing/Feridoon Sergizzarea

MTIC INTERCERT Certification Body

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