



Certificate OF REGISTRATION

We hereby declare that an examination of the under mentioned full quality assurance system has been carried out following the requirements of the national legislation to which the undersigned is subjected, transposing annex II (with the exemption of section 4) of the Directive 93/42/EEC, as amended by 2007/47/EC on medical devices.

Manufacturer and Facility

HARDIK INTERNATIONAL

Plot No. G-2041-42/A, Kishan Gate, Lodhika G.I.D.C
Kalawad Road, Metoda-360021, Rajkot, (INDIA)

Products(s)

Orthopedic Implants

Product type(s)

See Annex 1

Trade Mark

HARDIK

Classification of medical device

Medical Devices- Class IIb

Scope of quality system

Quality of design, production, storage and distribution
Of Orthopedic Implants

Certificate number

QSA-1604837

Date of issue

01-04-2019

Date of the end of validity

31-03-2022



We have audited the quality system in accordance with the Directive 93/42/EEC, as amended by 2007/47/EC annex II (3) and found that the quality system meet the requirements of the Directive 93/42/EEC, as amended by 2007/47/EC Annex II

(Further description of the products covered by this certificate are given in the annexure attached)



Quality System Assessment
International Limited
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Startford Ray

Certification Manager



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