



US CERTIFICATION & INSPECTION LIMITED



Company Number-13917497

Certificate of Compliance

CE

We hereby declare that the technical file of product complied with the requirement of the Directive Class-II and Class-III, Medical Devices Directive 93/42/EEC.

Manufacturer Name: ORTHREX LIFE CARE

Address: PLOT NO I/1, SAYAN TEXTILE PARK, HAJIRA ROAD, CHCHHAPOR, SURAT, GUJARAT, 394510

Products: Orthopaedic Implants: Intramedullary Nails, Bone Screws, Bone Plates, Wires & Pins, (More Details As per Annexure)

The certification body has performed an audit of the above product quality system covering the design, manufacture and final inspection of the certified product. The quality system has been assessed, approved and is subject to continuous surveillance according to Directive Class-II and Class-III, Medical Devices Directive 93/42/EEC.

The certificate is issued under the following conditions:

1. It applies only to the quality system maintained in the manufacture of above referenced models and it does not substitute the design or type examination procedures, if requested.
2. The certificate remains valid until the manufacturing conditions or the quality systems. changed. The certificate validity is conditioned by positive surveillance audits.
4. The CE mark as shown above can be used, under responsibility of the manufacturer, after completion of an EC declaration of conformity and compliance with all relevant EC directives. The statement is based on a single evaluation of one sample of above mentioned product. It does not imply. assessment of the whole production

Certificate Number: CE-6477

Validity of this certificate can be verified at www.uscertifications.co.uk.

Date of Certification:

08th April 2026

1st Surveillance Audit Due:

07th April 2027

2nd Surveillance Audit Due:

07th April 2028

Certificate expiry: (Subject to the Company

07th April 2029

Maintaining its system as per the required standard)

Authorised Signatory



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E mail ID: info@uscertifications.co.uk , web site: www.uscertifications.co.uk



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Certificate of Compliance **Annexure-1**

Product(s)

VARIABLEANGLELOW-BENDDISTALMEDIALTIBIALOCKINGPLATE3.5mmLEFT
PROXIMALMEDIALTIBIALOCKINGPLATE3.5mmLEFT
PROXIMALMEDIALTIBIALOCKINGPLATE3.5mmRIGHT
VARIABLEANGLEPROXIMALMEDIALTIBIALOCKINGPLATE3.5mmLEFT
VARIABLEANGLEPROXIMALMEDIALTIBIALOCKINGPLATE3.5mmRIGHT
DISTALRADIUSLOCKINGPLATESTRAIGHT2.4mm,2.7 mm
DISTALRADIUSLOCKINGPLATE2HOLEANGLEDHEAD2.4mm,2.7mmLEFT
DISTALRADIUSLOCKINGPLATE2HOLEANGLEDHEAD2.4mm,2.7mmRIGHT
L-DISTALRADIUSLOCKINGPLATEANGLED2.4mm,2.7mmLEFT
L-DISTALRADIUSLOCKINGPLATEANGLED2.4mm,2.7mmRIGHT
VARIABLEANGLEL-DISTALRADIUSLOCKINGPLATEANGLED2.4mm,2.7mmLEFT
VARIABLEANGLEL-DISTALRADIUSLOCKINGPLATEANGLED2.4mm,2.7mmRIGHT
T-DISTALRADIUSLOCKINGPLATE2.4mm,2.7 mm
L-DISTALRADIUSLOCKINGPLATEOBLIQUEANGLED2.4mm,2.7mmLEFT
L-DISTALRADIUSLOCKINGPLATEOBLIQUEANGLED2.4mm,2.7mmRIGHT
OPTIONALBUTTRESSLOCKINGPLATE2.4mm,2.7mmLEFT
OPTIONALBUTTRESSLOCKINGPLATE2.4mm,2.7mmRIGHT
VARIABLEANGLEOPTIONALBUTTRESSLOCKINGPLATE2.4mm,2.7mmLEFT
VARIABLEANGLEOPTIONALBUTTRESSLOCKINGPLATE2.4mm,2.7mmRIGHT
DISTALRADIUSLOCKINGPLATE3HOLES SHAFT5HOLESHEAD2.4mm,2.7mmLEFT
DISTALRADIUSLOCKINGPLATE3HOLES SHAFT5HOLESHEAD2.4mm,2.7mmRIGHT
DISTALRADIUSLOCKINGPLATEEXTRA-ARTICULAR5HOLESHEAD2.4mm,2.7mmLEFT
DISTALRADIUSLOCKINGPLATEEXTRA-ARTICULAR5HOLESHEAD2.4mm,2.7mmRIGHT
VARIABLEANGLEDISTALRADIUSLOCKINGPLATEEXTRA-ARTICULAR5HOLESHEAD2.4mm,2.7mmLEFT
VARIABLEANGLEDISTALRADIUSLOCKINGPLATEEXTRA-ARTICULAR5HOLESHEAD2.4mm,2.7mmRIGHT
DISTALRADIUSLOCKINGPLATEEXTRA-ARTICULAR4HOLESHEAD2.4mm,2.7mmLEFT

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Certificate of Compliance Annexure-2

Product(s)

DISTALRADIUSLOCKINGPLATEEXTRA-ARTICULAR4HOLESHEADHOLES2.4mm,2.7mmRIGHT
VARIABLEANGLEDISTALRADIUSLOCKINGPLATEEXTRA-ARTICULAR4HOLESHEAD2.4mm,2.7mmLEFT
VARIABLEANGLEDISTALRADIUSLOCKINGPLATEEXTRA-ARTICULAR4HOLESHEAD2.4mm,2.7mmRIGHT
ONE-THIRDTUBULARPLATE4to14HOLES3.5mm
RECONSTRUCTIONPLATES3to24HOLES3.5mm,4.0mm
RECONSTRUCTIONPLATES3to24HOLES4.5mm
VARIABLEANGLEDISTALRADIUSLOCKINGPLATE2.4mm,2.7mmLEFT
VARIABLEANGLEDISTALRADIUSLOCKINGPLATE2.4mm,2.7mmRIGHT
DISTALMEDIALTIBIALOCKINGPLATEwithTAB3.5mm,4.0mmLEFT
DISTALMEDIALTIBIALOCKINGPLATEwithTAB3.5mm,4.0mmRIGHT
DISTALMEDIALTIBIALOCKINGPLATE3.5mmLEFT
DISTALMEDIALTIBIALOCKINGPLATE3.5mmRIGHT
VARIABLEANGLEDISTALMEDIALTIBIALOCKINGPLATE3.5mmLEFT
VARIABLEANGLEDISTALMEDIALTIBIALOCKINGPLATE3.5mmRIGHT
VARIABLEANGLESUPERIORANTERIORCLAVICLELOCKINGPLATE2.7mmLEFT
VARIABLEANGLESUPERIORANTERIORCLAVICLELOCKINGPLATE2.7mmRIGHT
VARIABLEANGLESUPERIORANTERIORCLAVICLELOCKINGPLATE3.5mmLEFT
VARIABLEANGLESUPERIORANTERIORCLAVICLELOCKINGPLATE3.5mmRIGHT
CALCANEALPLATE3.5mm,4.0mm
DISTALFIBULARLOCKINGPLATE
PROXIMALFEMORALLOCKINGPLATELEFT
PROXIMALFEMORALLOCKINGPLATERIGHT
DISTALLATERALFEMORALLOCKINGPLATELEFT
DISTALLATERALFEMORALLOCKINGPLATERIGHT
PROXIMALLATERALTIBIALOCKINGPLATE5.5mmLEFT
PROXIMALLATERALTIBIALOCKINGPLATE5.5mmRIGHT

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Certificate of Compliance **Annexure-3**

Product(s)

OLECRANONPLATE3.5mmLEFT
OLECRANONPLATE3.5mmRIGHT
EXTRA-ARTICULARDISTALHUMERUSLOCKINGPLATE3.5mmLEFT
EXTRA-ARTICULARDISTALHUMERUSLOCKINGPLATE3.5mmRIGHT
PERIARTICULARPROXIMALHUMERUSLOCKINGPLATE3.5mmLEFT
PERIARTICULARPROXIMALHUMERUSLOCKINGPLATE3.5mmRIGHT
VARIABLEANGLEPERIARTICULARPROXIMALHUMERUSLOCKINGPLATE3.5mmLEFT
VARIABLEANGLEPERIARTICULARPROXIMALHUMERUSLOCKINGPLATE3.5mmRIGHT
CLAVICLEHOOKPLATE3.5mmLEFT
CLAVICLEHOOKPLATE3.5mmRIGHT
SUPERIORANTERIORCLAVICLEPLATE2.7mm,3.5mmLEFT
SUPERIORANTERIORCLAVICLEPLATE2.7mm,3.5mm RIGHT
SUPERIORANTERIORCLAVICLELOCKINGPLATES-SHAPE3.5mmLEFT
SUPERIORANTERIORCLAVICLELOCKINGPLATES-SHAPE3.5mmRIGHT
T-PLATELOCKING4HOLESHEAD3.5mmSMALL
PROXIMALLATERALTIBIALOCKINGPLATE3.5mmLEFT
PROXIMALLATERALTIBIALOCKINGPLATE3.5mmRIGHT
VARIABLEANGLEPROXIMALLATERALTIBIALOCKINGPLATELEFT
VARIABLEANGLEPROXIMALLATERALTIBIALOCKINGPLATERIGHT
POSTERIORPROXIMALMEDIALTIBIALOCKINGPLATE
VARIABLEANGLEPOSTERIORPROXIMALMEDIALTIBIALOCKINGPLATE
LATERALDISTALFIBULALOCKINGPLATE2.7mm,3.5mmLEFT
LATERALDISTALFIBULALOCKINGPLATE2.7mm,3.5mmRIGHT
VARIABLEANGLELATERALDISTALFIBULALOCKINGPLATE2.7mm,3.5mmLEFT
VARIABLEANGLELATERALDISTALFIBULALOCKINGPLATE2.7mm,3.5mmRIGHT
RADIALHEADNECKLOCKINGPLATE2.4mm

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