



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-6473

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



This certificate is property of US Certification & Inspection Limited and shall be returned immediately on request,

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Certificate of Compliance **Annexure-1**

Product(s)

VARIABLEANGLELOCKINGHEADSCREW(SELFTAPPING)Diameter2.4,2.7mm
6.0mm,8.0mm,10mm,12mm,14mm,16mm,18mm,20mm,22mm,24mm,26mm,28mm,30mm, 32mm,34mm,36mm,38mm,40mm
PROXIMALFEMORALLAGSCREWCANNULATEDDiameter8.0mm
60mm,65mm,70mm,75mm,80mm,85mm,90mm,95mm,100mm,105mm,110mm,115mm, 120mm
LAGSCREWCANNULATEDFORPROXIMALFEMORAL&ANTEGRADEFEMORALNAILDiameter6.4mm
60mm,65mm,70mm,75mm,80mm,85mm,90mm,95mm,100mm,105mm,110mm,115mm, 120mm
CORTEXSCREW(SELFTAPPING)Diameter4.5mm
10mm,12mm,14mm,16mm,18mm,20mm,22mm,24mm,26mm,28mm,30mm,32mm,34mm, 36mm,38mm,40mm,42mm,44mm,46mm,48mm,50mm,52mm,54mm,56mm,58mm,60mm, 62mm,64mm,66mm,68mm,70mm,72mm,74mm,76mm,78mm,80mm,85mm,90mm,95mm, 100mm
CORTEXSCREW(SELFTAPPING)withCRUCIFORMHEADDiameter1.5mm
6.0mm,8.0mm,10mm,12mm,14mm,16mm,18mm,20mm,22mm,24mm,26mm,28mm,30mm, 35mm,40mm,45mm,50mm,55mm,60mm,65mm,70mm
CORTEXSCREW(SELFTAPPING)withSTARDRIVEHEADDiameter1.5mm
6.0mm,8.0mm,10mm,12mm,14mm,16mm,18mm,20mm,22mm,24mm,26mm,28mm,30mm, 35mm,35mm,45mm,50mm,55mm,60mm,65mm,70mm
CORTEXSCREW(SELFTAPPING)withCRUCIFORMHEADDiameter2.0mm
6.0mm,8.0mm,10mm,12mm,14mm,16mm,18mm,20mm,22mm,24mm,26mm,28mm,30mm, 35mm,40mm,45mm,50mm,55mm,60mm,65mm,70mm
CORTEXSCREW(SELFTAPPING)withSTARDRIVEHEADDiameter2.0mm
6.0mm,8.0mm,10mm,12mm,14mm,16mm,18mm,20mm,22mm,24mm,26mm,28mm,30mm, 35mm,40mm,45mm,50mm,55mm,60mm,65mm,70mm

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Certificate of Compliance Annexure-2

Product(s)

CORTEXSCREW(SELFTAPPING),withHEXAGONALHEADDiameter2.4mm
6.0mm,8.0mm,10mm,12mm,14mm,16mm,18mm,20mm,22mm,24mm,26mm,28mm,30mm,35mm,40mm,45mm,50mm,55mm,60mm,65mm,70mm
CORTEXSCREW(SELFTAPPING)withSTARDRIVEHEADDiameter2.4mm
6.0mm,8.0mm,10mm,12mm,14mm,16mm,18mm,20mm,22mm,24mm,26mm,28mm,30mm,35mm,40mm,45mm,50mm,55mm,60mm,65mm,70mm
CORTEXSCREW(SELFTAPPING)withSTARDRIVEHEADDiameter2.7mm
6.0mm,8.0mm,10mm,12mm,14mm,16mm,18mm,20mm,22mm,24mm,26mm,28mm,30mm,35mm,40mm,45mm,50mm,55mm,60mm,65mm,70mm
CORTEXSCREW(SELFTAPPING)withSTARDRIVEHEADDiameter3.5mm
6.0mm,8.0mm,10mm,12mm,14mm,16mm,18mm,20mm,22mm,24mm,26mm,28mm,30mm,35mm,40mm,45mm,50mm,55mm,60mm,65mm,70mm
CORTEXSCREW(SELFTAPPING)withSTARDRIVEHEADDiameter4.5mm
6.0mm,8.0mm,10mm,12mm,14mm,16mm,18mm,20mm,22mm,24mm,26mm,28mm,30mm,35mm,40mm,45mm,50mm,55mm,60mm,65mm,70mm
HERBERTSCREW/DOUBLECOMPRESSIONCANNULATEDSCREWDiameter2.5mm
6.0mm,8.0mm,10mm,12mm,14mm,16mm,18mm,20mm,22mm,24mm,26mm,28mm,30mm,35mm,40mm,45mm,50mm,55mm,60mm,65mm,70mm
HERBERTSCREW/DOUBLECOMPRESSIONCANNULATEDSCREWDiameter3.0mm
6.0mm,8.0mm,10mm,12mm,14mm,16mm,18mm,20mm,22mm,24mm,26mm,28mm,30mm,35mm,40mm,45mm,50mm,55mm,60mm,65mm,70mm
HERBERTSCREW/DOUBLECOMPRESSIONCANNULATEDSCREWDiameter3.5mm
6.0mm,8.0mm,10mm,12mm,14mm,16mm,18mm,20mm,22mm,24mm,26mm,28mm,30mm,35mm,40mm,45mm,50mm,55mm,60mm,65mm,70mm

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Certificate of Compliance Annexure-3

Product(s)

CANNULATEDCANCELOUSSCREW16mmTHREADED	Diameter6.5mm
6.0mm,8.0mm,10mm,12mm,14mm,16mm,18mm,20mm,22mm,24mm,26mm,28mm,30mm,35mm,40mm,45mm,50mm,55mm,60mm,65mm,70mm	
CANNULATEDCANCELOUSSCREW32mmTHREADED	Diameter6.5mm
6.0mm,8.0mm,10mm,12mm,14mm,16mm,18mm,20mm,22mm,24mm,26mm,28mm,30mm,35mm,40mm,45mm,50mm,55mm,60mm,65mm,70mm	
CANNULATEDCANCELOUSSCREWFULLYTHREADED	Diameter6.5mm
6.0mm,8.0mm,10mm,12mm,14mm,16mm,18mm,20mm,22mm,24mm,26mm,28mm,30mm,35mm,40mm,45mm,50mm,55mm,60mm,65mm,70mm	
CANNULATEDCANCELOUSSCREW16mmTHREADED	Diameter7.3mm
6.0mm,8.0mm,10mm,12mm,14mm,16mm,18mm,20mm,22mm,24mm,26mm,28mm,30mm,35mm,40mm,45mm,50mm,55mm,60mm,65mm,70mm	
CANNULATEDCANCELOUSSCREW32mmTHREADED	Diameter7.3mm
6.0mm,8.0mm,10mm,12mm,14mm,16mm,18mm,20mm,22mm,24mm,26mm,28mm,30mm,35mm,40mm,45mm,50mm,55mm,60mm,65mm,70mm	
CANNULATEDCANCELOUSSCREWFULLYTHREADED	Diameter7.3mm
6.0mm,8.0mm,10mm,12mm,14mm,16mm,18mm,20mm,22mm,24mm,26mm,28mm,30mm,35mm,40mm,45mm,50mm,55mm,60mm,65mm,70mm	
LOCKINGCORTEXSCREW(SELFTAPPING)withSTARDRIVEHEAD	Diameter1.5mm
6.0mm,8.0mm,10mm,12mm,14mm,16mm,18mm,20mm,22mm,24mm,26mm,28mm,30mm,35mm,40mm,45mm,50mm,55mm,60mm,65mm,70mm	
LOCKINGCORTEXSCREW(SELFTAPPING)withSTARDRIVEHEAD	Diameter2.0mm
6.0mm,8.0mm,10mm,12mm,14mm,16mm,18mm,20mm,22mm,24mm,26mm,28mm,30mm,35mm,40mm,45mm,50mm,55mm,60mm,65mm,70mm	

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