



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-6468

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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Certificate of Compliance **Annexure-1**

Product(s)

1.BONESCREWS
MINICORTEXSREW Diameter 2.7mm
SIZES: 6.0mm, 8.0mm, 10mm, 12mm, 14mm, 16mm, 18mm, 20mm, 22mm, 24mm, 26mm, 28mm, 30mm, 32mm, 34mm, 36mm, 38mm, 40mm
CORTEXSREW (SELFTAPPING) Diameter 3.5mm X 20TPI
SIZES: 10mm, 12mm, 14mm, 16mm, 18mm, 20mm, 22mm, 24mm, 26mm, 28mm, 30mm, 32mm, 34mm, 36mm, 38mm, 40mm, 42mm, 44mm, 46mm, 48mm, 50mm, 55mm, 60mm, 65mm, 70mm, 75mm, 80mm, 85mm, 90mm
CORTEXSREW (SELFTAPPING) Diameter 3.5mm X 14TPI
SIZES: 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
CORTEXSREW (SELFTAPPING) Diameter 4.5mm X 1.75 Pitch
SIZES: 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, 82mm, 84mm, 86mm, 88mm, 90mm, 92mm, 94mm, 96mm, 98mm, 100mm
CANCELLOUSSREW PARTIALLY THREADED Diameter 4.0mm
SIZES: 12mm, 14mm, 16mm, 18mm, 20mm, 22mm, 24mm, 26mm, 28mm, 30mm, 35mm, 40mm, 45mm, 50mm, 55mm, 60mm, 65mm, 70mm, 75mm, 80mm
CANCELLOUSSREW FULLY THREADED Diameter 4.0mm
SIZES: 12mm, 14mm, 16mm, 18mm, 20mm, 22mm, 24mm, 26mm, 28mm, 30mm, 35mm, 40mm, 45mm, 50mm, 55mm, 60mm, 65mm, 70mm, 75mm, 80mm
CANCELLOUSSREW 16mm THREADED Diameter 6.5mm
SIZES: 25mm, 30mm, 35mm, 40mm, 45mm, 50mm, 55mm, 60mm, 65mm, 70mm, 75mm, 80mm, 85mm, 90mm, 95mm, 100mm, 105mm, 110mm, 115mm, 120mm

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Certificate of Compliance

Annexure-2

Product(s)

CANCELLOUSSCREW32mmTHREADED	Diameter6.5mm
40mm,45mm,50mm,55mm,60mm,65mm,70mm,75mm,80mm,85mm,90mm,95mm, 100mm,105mm,110mm,115mm,120mm	
WASHERforScrewDiameter2.7,3.5,4.0mm	
7.0mm	
WASHERforScrewDiameter4.5,6.5,7.0mm	
13mm	
CANCELLOUSSCREWFULLYTHREADED	Diameter6.5mm
30mm,35mm,40mm,45mm,50mm,55mm,60mm,65mm,70mm,75mm,80mm,85mm, 90mm,95mm,100mm	
CANNULATEDCANCELLOUSSCREWPARTIALLYTHREADED	Diameter4.0,4.5mm
12mm,14mm,16mm,18mm,20mm,22mm,24mm,26mm,28mm,30mm,35mm,40mm,45mm, 50mm,55mm,60mm,65mm,70mm	
CANNULATEDCANCELLOUSSCREWFULLYTHREADED	Diameter4.0,4.5mm
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	
CANNULATEDCANCELLOUSSCREW16mmTHREADED	Diameter6.5,7.0,7.3mm
40mm,45mm,50mm,55mm,60mm,65mm,70mm,75mm,80mm,85mm,90mm,95mm, 100mm,105mm,110mm,115mm,120mm	
CANNULATEDCANCELLOUSSCREW32mmTHREADED	Diameter6.5,7.0,7.3mm
50mm,55mm,60mm,65mm,70mm,75mm,80mm,85mm,90mm,95mm,100mm,105mm, 110mm,115mm,120mm	
CANNULATEDCANCELLOUSSCREWFULLYTHREADED	Diameter6.5,7.0,7.3mm
25mm,30mm,35mm,40mm,45mm,50mm,55mm,60mm,65mm,70mm,75mm,80mm, 85mm,90mm	

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Certificate of Compliance Annexure-3

Product(s)

MALLEOLARSCREW	Diameter4.5mm
25mm,30mm,35mm,40mm,45mm,50mm,55mm,60mm,65mm,70mm,75mm,80mm	
SPACERWITHLOCKINGHEAD	
3.5,5.0mm	
MOUNTINGBLOCK	
3.5,5.0mm	
SPACERWITHLOCKINGHEAD	
4.5,5.0mm	
MOUNTINGBLOCK	
4.5,5.0mm,	
CORTEXLOCKINGHEADSCREW(SELFTAPPING)	Diameter5.0mm
25mm,30mm,35mm,40mm,45mm,50mm,55mm,60mm,65mm,70mm,75mm,80mm,85mm,90mm,95mm,100mm	
CORTEXLOCKINGHEADSCREW(SELFTAPPING)	Diameter5.5mm
25mm,30mm,35mm,40mm,45mm,50mm,55mm,60mm,65mm,70mm,75mm,80mm,85mm,90mm,95mm,100mm	
CANCELLOUSLOCKINGHEADSCREW(SELFTAPPING)16mmTHREADED	Diameter6.5mm
30mm,35mm,40mm,45mm,50mm,55mm,60mm,65mm,70mm,75mm,80mm,85mm,90mm,95mm,100mm,105mm,110mm	
CANCELLOUSLOCKINGHEADSCREW(SELFTAPPING)32mmTHREADED	Diameter6.5mm
30mm,35mm,40mm,45mm,50mm,55mm,60mm,65mm,70mm,75mm,80mm,85mm,90mm,95mm,100mm,105mm,110mm	
CANCELLOUSLOCKINGHEADSCREW(SELFTAPPING)FULLYTHREADED	Diameter6.5mm
30mm,35mm,40mm,45mm,50mm,55mm,60mm,65mm,70mm,75mm,80mm,85mm,90mm,95mm,100mm,105mm,110mm	

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