



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-6471

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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Company Number-13917497

Certificate of Compliance Annexure-1

Product(s)

VARIABLEANGLECANCELLOUSLOCKINGHEADSCREWwithHEXAGONALHEAD&STARHEAD Diameter4.0mm
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,65mm, 70mm,75mm,80mm,85mm,90mm
VARIABLEANGLECANCELLOUSLOCKINGHEADSCREW(SELFTAPPING)FULLYTHREADED Diameter5.0mm
25mm,30mm,35mm,40mm,45mm,50mm,55mm,60mm,65mm,70mm,75mm,80mm,85mm, 90mm
VARIABLEANGLECORTEXLOCKINGHEADSCREWwithHEXAGONALHEADDiameter3.5mm
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,65mm, 70mm,75mm,80mm,85mm,90mm
VARIABLEANGLECANCELLOUSLOCKINGHEADSCREWFULLYTHREADEDwithHEXAGONALHEAD Diameter4.0mm
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,65mm, 70mm,75mm,80mm,85mm,90mm
LOCKINGSCREWDiameter3.4mm
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
LOCKINGSCREWDiameter3.5mm
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
LOCKINGSCREWDiameter4.0mm
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

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Certificate of Compliance

Annexure-2

Product(s)

DOUBLE COMPRESSION CANNULATED SCREW Diameter 2.5, 3.5mm

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

I/L LOCKING SCREW Diameter 3.9mm

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

I/L LOCKING SCREW Diameter 4.9mm

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

I/L LOCKING SCREW Diameter 5.0mm

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

I/L LOCKING SCREW Diameter 4.0mm

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

CORTEX LOCKING HEAD SCREW (SELF TAPPING) Diameter 2.4mm

8.0mm, 10mm, 12mm, 14mm, 16mm, 18mm, 20mm, 22mm, 24mm, 26mm, 28mm, 30mm, 32mm, 34mm, 36mm, 38mm, 40mm, 42mm, 44mm, 46mm, 48mm, 50mm

CORTEX LOCKING HEAD SCREW (SELF TAPPING) Diameter 3.5mm

10mm, 12mm, 14mm, 16mm, 18mm, 20mm, 22mm, 24mm, 26mm, 28mm, 30mm, 35mm, 40mm, 45mm, 50mm, 54mm, 58mm, 62mm, 66mm, 70mm, 74mm, 78mm, 82mm, 86mm, 90mm

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Certificate of Compliance Annexure-3

Product(s)

CORTEXLOCKINGHEADSCREW(SELFTAPPING)Diameter5.0mm
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,82mm,84mm,86mm,88mm,90mm,94mm,98mm
CANCELLOUSLOCKINGHEADSCREWwithHEXAGONALHEAD&STARHEADDiameter4.0mm
20mm,22mm,24mm,26mm,28mm,30mm,35mm,40mm,45mm,50mm,55mm,60mm,65mm,70mm,75mm,80mm
LOCKINGHEADSCREW(SELFTAPPING)withHEXAGONALHEAD&STARHEADDiameter2.7mm
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
CANCELLOUSLOCKINGHEADSCREW(SELFTAPPING)Diameter5.0mm
25mm,30mm,35mm,40mm,45mm,50mm,55mm,60mm,65mm,70mm,75mm,80mm,85mm,90mm
CANCELLOUSSCREWWITHLOCKINGHEADDiameter4.0mm
20mm,25mm,30mm,35mm,40mm,45mm,50mm,55mm,60mm,65mm,70mm
CORTEXSCREW(SELFTAPPING)Diameter3.5mmX20TPI/1.25Pitch
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,82mm,84mm,86mm,88mm,90mm
HERBERTSCREW Diameter3.0,4.0mm
12mm,14mm,16mm,18mm,20mm,22mm,24mm,26mm,28mm,30mm,35mm,40mm,45mm,50mm,55mm,60mm,65mm,70mm

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