



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-6478

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)

RADIALHEADRIMPLATE2.4mm,2.7mmLEFT
RADIALHEADRIMPLATE2.4mm,2.7mmRIGHT
V.A.DISTALRADIUSTWOCOLUMNSVOLARLOCKINGPLATE2.4mm,2.7mm LEFT
V.A.DISTALRADIUSTWOCOLUMNSVOLARLOCKINGPLATE2.4mm,2.7mmRIGHT
CALCANEALLOCKINGPLATE3.5mm,4.0mmLEFT
CALCANEALLOCKINGPLATE3.5mm,4.0mmRIGHT
SPRINGPLATE3.5mm
RECONSTRUCTIONPELVICCURVEDPLATE88degreesRADIUS
RECONSTRUCTIONPELVICCURVEDPLATE108degreesRADIUS
RECONSTRUCTIONPELVICSTRAIGHTPLATE
J-TYPE RECONSTRUCTIONPELVICPLATE
STRAIGHTMETAPHYSEALLOCKINGPLATECOMBI-HOLES3.5mm
CLAVICLEDISTALLOCKINGPLATECOMBI-HOLESLEFT / RIGHT
HUMERALGREATERTUBEROSITYLOCKINGPLATELEFT / RIGHT
HUMERALDISTALLATERALLOCKINGPLATE3.5mmLEFT / RIGHT
HUMERALDISTALSUBCONDYLARLOCKINGPLATELEFT / RIGHT
RADIUSDISTALDIAPHYSEALLOCKINGPLATECOMBI-HOLES
OLECRANONIILOCKINGPLATECOMBI-HOLES,
WRISTDISTALDIAPHYSEALLOCKINGPLATECOMBI-HOLESSHORT
WRISTDISTALDIAPHYSEALLOCKINGPLATECOMBI-HOLESSTRAIGHT
FEMORALPROXIMALLOCKINGPLATESMALLLEFT / RIGHT
FEMORALDISTALLATERALSUBCONDYLARLOCKINGPLATELEFT / RIGHT
FEMORALDISTALMEDIALSUBCONDYLARLOCKINGPLATELEFT / RIGHT
FEMORALDISTALMEDIALCONDYLARLOCKINGPLATELEFT / RIGHT
TIBIALPROXIMALLATERALLOCKINGPLATEII3.5mmLEFT / RIGHT
TIBIALPROXIMALLATERALLOCKINGPLATEIII3.5mmLEFT / RIGHT

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Certificate of Compliance

Annexure-2

Product(s)

TIBIALPROXIMALMEDIALLOCKINGPLATEII3.5mmLEFT/RIGHT
TIBIALPROXIMALMEDIALLOCKINGPLATE5.0mmLEFT/RIGHT
TIBIALPROXIMALPOSTERIORLOCKINGPLATEII3.5mmLEFT/RIGHT
TIBIALDISTALLATERALLOCKINGPLATEII3.5mmLEFT/RIGHT
TIBIALDISTALMEDIALLOCKINGPLATE3.5mm,5.0mm LEFT/RIGHT
FIBULARDISTALLOCKINGPLATEIIILEFT/RIGHT
FIBULARDISTALPOSTERIORLOCKINGPLATELEFT/RIGHT
ANKLEFUSIONLOCKINGPLATELEFT/RIGHT
CALCANEALSMALLLOCKINGPLATELEFT/RIGHT
CALCANEALLOCKINGPLATEIIILEFT/RIGHT
CALCANEALLOCKINGPLATEIIILEFT/RIGHT
TUBEROSITYCALCANEALLOCKINGPLATE
L-TYPELOCKINGPLATE
MICROXLOCKINGPLATE4HOLES
MICROLOCKINGPLATE2/4HOLES
MICRO1stMETATARSOPHALANGEALLOCKINGPLATE6HOLES2.4mm,2.7mm LEFT/RIGHT
MICROCLOVERLEAFLOCKINGPLATE2/4HOLES2.4mm,2.7mm
MICROTLOCKINGPLATE2/4/7HOLES2.4mm,2.7mmSHORT/STANDARD/LONG/EXTRALONG
3.INTRAMEDULLARYNAILS
HUMERUSINTERLOCKINGNAILDiameter6.5mm
HUMERUSINTERLOCKINGNAILDiameter7.5mm
PLUGCAPFORHUMERUSI/LNAIL
SMPLUNIVERSALTIBIAINTERLOCKINGNAILDiameter8.0mmX260mmto380mm
SMPLUNIVERSALTIBIAINTERLOCKINGNAILDiameter9.0mmX260mmto380mm
SMPLUNIVERSALTIBIAINTERLOCKINGNAILDiameter10mmX260mmto380mm

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Certificate of Compliance Annexure-3

Product(s)

SMPLUNIVERSALTIBIAINTERLOCKINGNAILDiameter11mmX260mmto380mm
SMPLUNIVERSALTIBIAINTERLOCKINGNAILDiameter12mmX260mmto380mm
SMPLUNIVERSALFEMURINTERLOCKINGNAILDiameter9.0mmX360mmto480mm
SMPLUNIVERSALFEMURINTERLOCKINGNAILDiameter10mmX360mmto480mm
SMPLUNIVERSALFEMURINTERLOCKINGNAILDiameter11mmX360mmto480mm
SMPLUNIVERSALFEMURINTERLOCKINGNAILDiameter12mmX360mmto480mm
SMPLUNIVERSALFEMURINTERLOCKINGNAILDiameter13mmX360mmto480mm
ENDCAPFORFEMURNAIL
APFNSPIRALBLADEDiameter10.5mmX70mmto130mm
APFNAUGMENTABLEHELICALBLADEDiameter12.5mmX70mmto130mm
APFNAUGMENTABLESCREWDiameter10.5mmX70mmto130mm
CANNULATEDSETSCREW
MULTILOCENDCAP0mmto15mm
SMPLPROXIMALFEMORALNAILDiameter9.0mmSHORTNAIL(PFNTYPE)
SMPLPROXIMALFEMORALNAILDiameter10mmSHORTNAIL(PFNTYPE)
SMPLPROXIMALFEMORALNAILDiameter11mmSHORTNAIL(PFNTYPE)
SMPLPROXIMALFEMORALNAILDiameter12mmSHORTNAIL(PFNTYPE)
SMPLPROXIMALFEMORALNAILDiameter9.0mmLONG(PFNTYPE)LEFT
SMPLPROXIMALFEMORALNAILDiameter9.0mmLONG(PFNTYPE)RIGHT
SMPLPROXIMALFEMORALNAILDiameter10mmLONG(PFNTYPE)LEFT / RIGHT
SMPLPROXIMALFEMORALNAILDiameter11mmLONG(PFNTYPE)LEFT / RIGHT
SMPLPROXIMALFEMORALNAILDiameter12mmLONG(PFNTYPE)LEFT / RIGHT
ENDCAPforPROXIMALFEMORALNAIL2.0mmto20mm
TROCHANTERICFIXATIONNAIL130degreesDiameter9.0mm
TROCHANTERICFIXATIONNAIL135degreesDiameter9.0mm
TROCHANTERICFIXATIONNAIL130degreesDiameter10mm

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Certificate of Compliance Annexure-4

Product(s)

CANNULATED CANCELLOUS LOCKING HEAD SCREW (SELF TAPPING) FULLY THREADED Diameter 6.5mm
40mm, 45mm, 50mm, 55mm, 60mm, 65mm, 70mm, 75mm, 80mm, 85mm, 90mm, 95mm, 100mm, 105mm, 110mm
CORTEX LOCKING HEAD SCREW with HEXAGONAL HEAD Diameter 3.5 mm
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, 95mm, 100mm
CANCELLOUS LOCKING SCREW FULLY THREADED with HEXAGONAL HEAD & STAR HEAD Diameter 4.0 mm
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, 95mm, 100mm
VARIABLE ANGLE CORTEX LOCKING HEAD SCREW (SELF TAPPING) with HEXAGONAL HEAD & STAR HEAD Diameter 2.7mm
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
VARIABLE ANGLE CORTEX LOCKING HEAD SCREW (SELF TAPPING) with HEXAGONAL HEAD & STAR HEAD Diameter 3.5mm
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, 60 mm,
VARIABLE ANGLE CORTEX LOCKING HEAD SCREWS (SELF TAPPING) with HEXAGONAL HEAD & STAR HEAD Diameter 4.5, 5.0mm
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, 95mm, 100mm

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Certificate of Compliance

Annexure-5

Product(s)

TROCHANTERICFIXATIONNAIL135degreesDiameter10mm
TROCHANTERICFIXATIONNAIL130degreesDiameter11mm
TROCHANTERICFIXATIONNAIL135degreesDiameter11mm
TROCHANTERICFIXATIONNAIL130degreesDiameter12mm
TROCHANTERICFIXATIONNAIL135degreesDiameter12mm
PROXIMALFEMORALANTIROTATIONNAIL(APFN TYPE)Diameter10mmSHORT
PROXIMALFEMORALANTIROTATIONNAIL(APFN TYPE)Diameter11mmSHORT
PROXIMALFEMORALANTIROTATIONNAIL(APFN TYPE)Diameter12mmSHORT
PROXIMALFEMORALANTIROTATIONNAIL(APFN TYPE)Diameter10mmLEFTLONG
PROXIMALFEMORALANTIROTATIONNAIL(APFN TYPE)Diameter10mmRIGHTLONG
PROXIMALFEMORALANTIROTATIONNAIL(APFN TYPE)Diameter11mmLEFTLONG
PROXIMALFEMORALANTIROTATIONNAIL(APFN TYPE)Diameter11mmRIGHTLONG
PROXIMALFEMORALANTIROTATIONNAIL(APFN TYPE)Diameter12mmLEFTLONG
PROXIMALFEMORALANTIROTATIONNAIL(APFN TYPE)Diameter12mmRIGHTLONG
PERFECTINTERTROCHANTERICANTEGRADENAIL(SHORT)9.0mm
PERFECTINTERTROCHANTERICANTEGRADENAIL(SHORT)10mm
PERFECTINTERTROCHANTERICANTEGRADENAIL(SHORT)11mm
PERFECTINTERTROCHANTERICANTEGRADENAIL(SHORT)12mm
PERFECTINTERTROCHANTERICANTEGRADENAIL(LONG)LEFT9.0mm
PERFECTINTERTROCHANTERICANTEGRADENAIL(LONG)RIGHT9.0mm
PERFECTINTERTROCHANTERICANTEGRADENAIL(LONG)LEFT10mm
PERFECTINTERTROCHANTERICANTEGRADENAIL(LONG)RIGHT10mm
PERFECTINTERTROCHANTERICANTEGRADENAIL(LONG)LEFT11mm
PERFECTINTERTROCHANTERICANTEGRADENAIL(LONG)RIGHT11mm
PERFECTINTERTROCHANTERICANTEGRADENAIL(LONG)LEFT12mm
PERFECTINTERTROCHANTERICANTEGRADENAIL(LONG)RIGHT12mm

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Certificate of Compliance

Annexure-6

Product(s)

ENDCAPFORPAIN
MULTILOCPROXIMALHUMERALNAILDiameter6.5mmLEFT
MULTILOCPROXIMALHUMERALNAILDiameter6.5mmRIGHT
MULTILOCPROXIMALHUMERALNAILDiameter7.5mmLEFT
MULTILOCPROXIMALHUMERALNAILDiameter7.5mmRIGHT
ENDCAPFORANTIGRADEFEMORALNAIL
SMPLSMARTFEMURNAILDiameter9.0mmSHORT
SMPLSMARTFEMURNAILDiameter10mmSHORT
SMPLSMARTFEMURNAILDiameter11mmSHORT
SMPLSMARTFEMURNAILDiameter9.0mmLEFTLONG
SMPLSMARTFEMURNAILDiameter10mmLEFTLONG
SMPLSMARTFEMURNAILDiameter11mmLEFTLONG
SMPLSMARTFEMURNAILDiameter9.0mmRIGHTLONG
SMPLSMARTFEMURNAILDiameter10mmRIGHTLONG
SMPLSMARTFEMURNAILDiameter11mmRIGHTLONG
PLUGCAPFORSMARTFEMURNAIL
ELASTICNAILDIAMETER2.0mm,2.5mm,3.0mm,3.5mm,4.0mmX450mm
TELESCOPICNAILDIAMETER1.9mm,2.4mm,3.0mm,3.4mm,3.5mm,4.0mm,4.8mm,5.5mm, 6.5mmX450mm
ENDERSNAIL
RUSHNAILFORRADIUSANDULNA
SMPLPERFECTTIBIANAILCANNULATEDDiameter8.0mm
SMPLPERFECTTIBIANAILCANNULATEDDiameter.9.0mm
SMPLPERFECTTIBIANAILCANNULATEDDiameter10mm
SMPLPERFECTTIBIANAILCANNULATEDDiameter11mm
SMPLPERFECTTIBIANAILCANNULATEDDiameter12mm
ENDCAPFORPERFECTTIBIANAIL

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Certificate of Compliance Annexure-7

Product(s)

SUPRACONDYLARNAILDiameter9.0mm

SUPRACONDYLARNAILDiameter10mm

SUPRACONDYLARNAILDiameter11mm

SUPRACONDYLARNAILDiameter12mm

PFNABLADE70mmto120mm

4.WIRES&PINS

KIRSCHNERWIRE1.0mm,1.5mm,2.0mm,2.5mm,3.0mm

KIRSCHNERWIRETHREADED1.0mm,1.5mm,2.0mm,2.5mm,3.0mm

STEINMANNPIN3.5mm,4.0mm,4.5mm,5.0mm

STAINLESSSTEELWIREREEL

SCHANZSCREW2.5mm,3.5mm,4.5mm,5.0mm

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