



Certificate No. CFG-NE2079-8-2025-1

**CERTIFICATE TO FOREIGN GOVERNMENT
FOR DEVICE NOT EXPORTED FROM THE UNITED STATES**

The U.S. Food and Drug Administration (FDA) certifies the following information concerning the device(s) listed below to be shipped from GERMANY into foreign countries.

Name of Device(s)

See Attached List

(Three Pages)

Name of Manufacturer, Address

See Attached List

(One Page)

The device(s) described above (and the manufacturing site(s) which produces it) is subject to the jurisdiction of the FDA under the Federal Food, Drug, and Cosmetic Act (FD&C Act).

It is certified that the above device(s) may be marketed in the United States of America at this time. The manufacturing establishment(s) in which the device(s) is produced is subject to periodic inspections.

Sincerely,

CDR Cesar A. Perez, PhD, Director
DRP2: Division of Establishment Support
Office of Regulatory Programs
Office of Product Evaluation and Quality
Center for Devices and Radiological Health
U.S. Food and Drug Administration, DHHS

This certificate is valid from September 04, 2025 to September 03, 2027.



To verify the authenticity of the information on this certificate, you may scan the QR code or visit www.access.fda.gov/fecv/CDRH.



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Certificate to Foreign Government for Device not Exported from the United States - Name of Manufacturer

Attachment Page 1 of 1

Name of Owner Operator

KAUL MEDIZINTECHNIK GMBH

Konigsberger Street 40

Dierdorf, Rhineland-Palatinate

GERMANY 56269

Name of Manufacturer

KAUL MEDIZINTECHNIK GMBH

Konigsberger Street 40

Dierdorf, Rhineland-Palatinate

GERMANY 56269

----END OF MANUFACTURER LIST----





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Name of Owner Operator

KAUL MEDIZINTECHNIK GMBH
Königsberger Street 40
Dierdorf, Rhineland-Palatinate
GERMANY 56269

Name of Manufacturer

KAUL MEDIZINTECHNIK GMBH
Königsberger Street 40
Dierdorf, Rhineland-Palatinate
GERMANY 56269

Name of Product(s)

Knee Arthroscopy System
Suture Holder With Tensioner
Transportal Femoral Offset Guide, 5mm
Transportal Femoral Offset Guide, 6mm
Transportal Femoral Offset Guide, 7mm
Screwdriver for Polymer Interference Screw
Screwdriver for Ti Interference Screw, T25 Star Driver
Cannulated Headed Reamer, Ø4.7mm
Tibial Cannulated Reamer, Ø6mm
Tibial Cannulated Reamer, Ø6.5mm
Tibial Cannulated Reamer, Ø7mm
Tibial Cannulated Reamer, Ø7.5mm
Tibial Cannulated Reamer, Ø8mm
Tibial Cannulated Reamer, Ø8.5mm
Tibial Cannulated Reamer, Ø9mm
Tibial Cannulated Reamer, Ø9.5mm
Tibial Cannulated Reamer, Ø10mm
Tibial Cannulated Reamer, Ø10.5mm
Tibial Cannulated Reamer, Ø11mm
Tibial Cannulated Reamer, Ø11.5mm
Tibial Cannulated Reamer, Ø12mm
Femoral Cannulated Reamer, Ø6mm
Femoral Cannulated Reamer, Ø6.5mm
Femoral Cannulated Reamer, Ø7mm
Femoral Cannulated Reamer, Ø7.5mm
Femoral Cannulated Reamer, Ø8mm
Femoral Cannulated Reamer, Ø8.5mm
Femoral Cannulated Reamer, Ø9mm
Femoral Cannulated Reamer, Ø9.5mm
Femoral Cannulated Reamer, Ø10mm
Femoral Cannulated Reamer, Ø10.5mm
Femoral Cannulated Reamer, Ø11mm
Femoral Cannulated Reamer, Ø11.5mm
Femoral Cannulated Reamer, Ø12mm
Drill Guide Handle
PCL Tibial Aimer with O Tip
ACL Tip C Aimer, Right
ACL Tip C Aimer, Left
ACL Tip O Aimer
ACL Tip Aimer
2.4mm Drill Guide Bullet
PCL Tibial Aimer
PCL Femoral Aimer
ACL Elbow Aimer
Nitinol Guide Wire Ø1.2mm x Length 300mm (For Interference Screws)





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Depth Gauge for Knee ACL/PCL Instrument
Transtibial Femoral Offset Guide, 5mm
Transtibial Femoral Offset Guide, 6mm
Transtibial Femoral Offset Guide, 7mm
Tendon Stripper (Closed End), Ø6mm
Tendon Stripper (Closed End), Ø7mm
Tendon Stripper (Closed End), Ø8mm
Tendon Stripper (Open End), Ø6mm
Tendon Stripper (Open End), Ø7mm
Tendon Stripper (Open End), Ø8mm
Quick Coupling T-Handle for Tunnel Dilator
Tunnel Dilator, Cannulated, Ø6 mm
Tunnel Dilator, Cannulated, Ø7 mm
Tunnel Dilator, Cannulated, Ø8 mm
Tunnel Dilator, Cannulated, Ø9 mm
Tunnel Dilator, Cannulated, Ø10 mm
Straight Rasp
Convex Rasp
Half-Round Rasp
Curette, 25° Angled Down
Knee Probe
Guide Pin, Trocar-Tip, Ø2.4mm x 355mm
Guide Pin, Drill Tip, Ø2.4mm x 355mm
Passing Pin Ø2.4mm x 250mm
Micro Fracture Awl, 0°
Micro Fracture Awl, 25°
Micro Fracture Awl, 40°
Micro Fracture Awl, 60°
Tunnel Plug, 7-8mm
Tunnel Plug, 8-9mm
Tunnel Plug, 9-10mm
Staple Impactor
PCL Elevator with wire capture hole
Ø4.5mm Cannulated Headed Reamer
Ratchet Handle for Hudson Coupling Screwdriver Shaft
Screwdriver Shaft for Ti Interference Screw, T25 Star Driver, Hudson Coupling
Screwdriver Shaft For Polymer Interference Screw, Hudson Coupling
4.5mm FlyKuter Guide Bullet
Graft Sizer, 4mm to 12mm (0.5mm steps)
Instrument Box
Tray A for Knee Arthroscopy Instruments
Tray B for Knee Arthroscopy Instruments
Tray C for Knee Arthroscopy Instruments
Tray D for Knee Arthroscopy Instruments
Container for Knee Arthroscopy Instruments
Lid for Container, Knee Arthroscopy Instrument Set
Graft Station Arthroscopy Instrument Set
Graft Station Board
Sliding base
Graft Grasper Clamp - Left
Graft Grasper Clamp - Right
Button Holder With Scale
Suture Holder With Tensioner
Graft Sizer, 4mm to 12mm (0.5mm steps)
Container for Graft Station Instrument Set
Lid for Container, Graft Station Instrument Set
Shoulder Arthroscopy System
8 Point Slotted Drill Guide, Length 190mm





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8 Point Slotted Drill Guide, Length 100mm

V-Mouth Drill Guide

8 Point Drill Guide

V-Mouth Drill Guide - Curve

Trocar Tip Obturator

Trocar Tip Obturator - Curve

Ø1.8mm X 200mm Drill Bit

Ø2.8mm X 200mm Drill Bit

Ø2.4mm X 200mm Drill Bit

Ø3.2mm X 200mm Drill Bit

Ø1.8mm X 300mm Drill Bit

Ø2.8mm X 300mm Drill Bit

Ø1.5mm X 300mm Drill Bit, Stainless Steel

Ø1.5mm X 300mm Drill Bit, Nitinol

Ø2.9mm Awl

Ø3.2mm Awl

Ø4.1mm Awl

Awl For 4.5/5.5mm PEEK Screw-In Anchor

Awl For 6.5mm PEEK Screw-In Anchor

Awl/Tap For 4.5/5.5mm PEEK Screw-In Anchor

Awl/Tap For 6.5mm PEEK Screw-In Anchor

Tap For 4.5/5.5mm PEEK Screw-In Anchor

Tap For 6.5mm PEEK Screw-In Anchor

4.5/5.5mm Knotless PEEK Anchor Driver

Switching Stick

Arthroscopic Probe - Shoulder

Tissue Elevator, 15° Up

Tissue Elevator, 15° Down

Rasp, 15° Up

Rasp, 15° Down

Ring Curette

Knot Pusher

Hammer

Ø2.4mm X 300 mm Drill Bit

Ø1.8mm X 325 mm Drill Bit

Ø2.5mm X 200 mm Drill Bit (For Knotless Anchor)

Ø3.2mm X 200 mm Drill Bit (For Knotless Anchor)

Ø2.4mm x 250 mm Passing Pin

Ø4.5mm Cannulated Headed Reamer

Graft Sizer, 6.0mm to 9.0mm (1.0mm Steps)

Ø 6.0mm Tocar Tip Headed Reamer

Ø7.0mm Tocar Tip Headed Reamer

Ø8.0mm Tocar Tip Headed Reamer

Ø9.0mm Tocar Tip Headed Reamer

Awl/Tap for 4.75/5.5mm Gyrolock Screw-In Anchor

Tap for 4.75/5.5mm Gyrolock Screw-In Anchor

Tap for 3.5mm Gyrolock Screw-In Anchor

Tray A for Shoulder Arthroscopy Instruments

Tray B for Shoulder Arthroscopy Instruments

Tray C for Shoulder Arthroscopy Instruments

Container for Shoulder Arthroscopy Instrument Set

Lid for Container, Shoulder Arthroscopy Instrument Set

-----END OF PRODUCT LIST-----

