



## Declaration of Conformity

EMDN CND Code : Y061299

Issue Date: Mar. 02, 2022

EMDN CND Description: Lower extremity orthoses - other

Valid Date: Dec. 31, 2025

This declaration of conformity is issued under the sole responsibility of the manufacturer:

OPPO Medical Inc., address at: Seattle City Center, 1420 Fifth Ave., Ste. 220080, Seattle, WA98101, USA

Single registration number (SRN): US-MF-000005202

Authorised Representative: MT Promedt Consulting GmbH, address at: Altenhofstrasse 80,  
D-66386 St. Ingbert Germany      Single registration number (SRN): DE-AR-000000085

The basic UDI-DI: 8402706CL102KV

We herewith declare that the products as referred to in Attachment I are in conformity with the requirements set out in the REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL.

Conformity Assessment Procedure: MDR (EU) 2017/745 Art 52. (7), ANNEX II (Technical documentation) & ANNEX III (Technical documentation on post-market surveillance)

Risk Classification of the Product: Class I    Rule: MDR (EU) 2017/745, Annex VIII, Section 4, 4.1, Rule 1 "All non-invasive devices are classified as class I."

Applied Standards: EN ISO13485:2016, EN1041:2008, EN ISO14971:2012, EN ISO 15223-1:2016,  
EN ISO 10993-1:2009, EN ISO10993-5:2009, EN ISO 22523:2006, EN 62366:2008,  
ISO 10993-10:2021, ISO 9001:2015

Intended purpose: The devices soothe pain and resolve strains, sprains, overstretch injuries, and joint malalignments. They provide compression and support injuries by keeping joints in a neutral position. They also retain heat to alleviate soft tissue adhesions.

Mar. 02, 2022/ Seattle

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Date/Place

  
.....  
Jackson Chiang  
President



Attachment 1

EMDN CND Code : Y061299

EMDN CND Description: Lower extremity orthoses – other

Knee

Reference number	Product Trade name
1021	Knee Support
1022	Knee Support
1023	Knee Support
1024	Knee Support
1028	Patella Tracking Support
1029	Patella Tendon Strap
1030	Knee Stabilizer
1031	Hinged Knee Stabilizer
1032	Post-Operative Knee Support
1033	Patella Stabilizer
1034	Patella Stabilizer
1035	Hinged Knee Stabilizer
1036	Multi Orthosis Knee Brace
1124	Knee Support
1125	Knee Support
1130	Adjustable Knee Stabilizer
1132	Contour Knee Support
1221	Knee Support
1230	Adjustable Knee Stabilizer
1231	Knee Guardian
1232	Knee Guardian
1429	Jumper's Strap W/Silicon Pad
2021	Open Patella Knee Support
2022	Knee Support
2029	Open Knee Brace
2030	Spiral Knee Support
2031	Hinged Knee Support
2034	Light Knee Stabilizer
2037	Hinged Knee Brace
2120	Knee Wrap
2123	X-Back Knee Brace
2133	Knee Stabilizer
2137	Hinged Knee Brace
2222	Knee Brace
2233	Open Patella Knee Stabilizer
2320	Knee Stabilizer
2321	Knee Support



2323	Premium C-pad Knee Stabilizer
2330	Hinged Knee Stabilizer
2331	Polycentric Knee Stabilizer
2438	Knee Immobilizer W/Silicone Pad
2520	Ceramic Knee Support
2523	Knee Support
2529	Nano Knee Support
2620	Biomagnetic Knee Support
2920	Knee Support
2921	Force-in-one Patella Stabilizer
2923	C-Knee Stabilizer
2924	Knee Protector
2930	Knee Poly-Stabilizer
3121	Genius-X Ligament Brace
4021	Elite Genu Adjustor
4030	Knee Immobilizer
4039	Motion Control Knee Splint
4139	Motion Control Knee Splint
4239	Excel Knee Brace
RK100	Knee Strap
RK101	Knee Support
RK102	Knee Brace
RK200	Knee Support

#### Ankle

Reference number	Product Trade name
1001	Ankle Support
1003	Ankle Support W/Strap
1004	Ankle Support
1008	Ankle Support
1009	Ankle Support W/Elastic Strap
1103	Adjustable Ankle Support
1109	Ankle Support W/Plastic Stay
1201	Ankle Support
1408	Achilles Brace With Silicone Pad
1409	Silicone Ankle Support
2001	Ankle Support
2003	Ankle Brace
2004	Ankle Support
2101	Ankle Wrap
2103	Ankle Brace
2201	Ankle Brace
2204	Ankle Brace



2302	Deluxe Ankle Stabilizer
2401	Stretchy Grip Wrap
2409	Ankle Support W/Silicone Pad
2502	Ankle Support
2504	Ceramic Ankle Support
2509	Nano Ankle Support
2601	Biomagnetic Ankle Support
2900	Ankle Support
2902	Ankle Protector
2903	Ankle Activator
2909	Ankle Stabilizer
3007	Short Walker With Fixed Ankle
3009	Standard Walker With Fixed Ankle
3108	Standard Walker With Rom Hinge
3109	Air Walker With Rom Hinge
4007	Ankle Support
4009	Air/ Lite Ankle Brace
4106	Ankle Support With Strap
4109	Ankle Brace With Cryo-Gel Pads
4206	Ankle Brace
RA100	Ankle Brace
RA200	Ankle Support
RA300	Ankle Stabilizer

#### Shin

Reference number	Product Trade name
1010	Shin Support
2010	Shin Support
2011	Firm Support Stocking

#### Thigh

Reference number	Product Trade name
1040	Thigh Support
2040	Thigh Support

#### Hip

Reference number	Product Trade name
2041	Hip Stabilizer