



Declaration of Conformity

EMDN CND Code : Y060699

Issue Date: Mar. 02, 2022

EMDN CND Description: Orthoses, upper extremity - 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: 8402706CL103KX

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


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Jackson Chiang
President



Attachment 1

EMDN CND Code : Y060699

EMDN CND Description: Orthoses, upper extremity - other

Shoulder

Reference number	Product Trade name
1072	Shoulder Support
2072	Shoulder Support
2172	Reinforced Shoulder Brace
2970	Shoulder Activator
4072	Humerus Brace

Elbow

Reference number	Product Trade name
1080	Elbow Support
1085	Elbow Support
1086	Tennis & Golf Elbow Wrap
1187	Hinged Elbow Support
1287	Hinged Elbow Support
1486	Tennis/Golf Elbow Strap W/Silicone Pad
1489	Tennis/Golf Elbow Strap W/Silicone Pad
2080	Elbow Support
2085	Elbow Support
2185	Elbow Wrap
2280	Elbow Brace
2385	Elbow Support
2580	Ceramic Elbow Support
2587	Elbow Support
2589	Nano Elbow Support
2685	Biomagnetic Elbow Support
2986	Elbow Support
2987	Elbow Epi-Reliever
2988	Elbow Protector
4080	Arm Immobilizer
4486	Tennis/Golf Elbow Support W/Silicone Pad
RE200	Elbow Support
RE300	Tennis Elbow Strap



Wrist

Reference number	Product Trade name
1081	Wrist Wrap
1082	Wrist Splint
1083	Wrist Wrap
1084	Wrist/Thumb Support
1088	Wrist/Thumb Support
1089	Wrist/Thumb Support
1180	Wrist/Thumb Support
1184	Wrist/Thumb Support
1188	Wrist/Thumb Support
1281	Wrist Wrap
1288	Wrist/ Thumb Support
1289	Wrist/Thumb Support
1389	Wrist/Thumb Support
2081	Wrist Wrap
2082	Splint Wrist Brace
2083	Wrist Wrap
2084	Palm Brace
2181	Wrist Wrap
2182	Wrist Splint W/Elastic Strap
2184	Wrist Thumb Brace
2281	Wrist Support
2288	Wrist Splint With Elastic Strap
2383	Thumb Loop Wristband
2384	Palmar Thumb Support
2387	Wrist Stabilizer
2388	Deluxe Wrist Stabilizer
2389	Thumb Stabilizer
2583	Wrist Support
2586	Nano Wrist Support
2681	Biomagnetic Wrist Support
2980	Wrist Support
2984	Wrist Stabilizer
3182	Elastic Wrist/Thumb Splint



4182	Wrist-hand Splint
4188	Wrist/Thumb Support
4288	Wrist Support
4380	Snug-fit Wrist Brace
4388	Sliding-fit Wrist Brace
RH100	Wrist Wrap
RH101	Wrist Wrap
RH300	Thumb Stabilizer
RH301	Wrist Splint
RH302	Wrist Splint

Finger

Reference number	Product Trade name
4280	Baseball Finger Splint
4281	Premium Finger Splint
4282	Curve Finger Splint
4283	Open Thimble Splint
4284	Finger Splint
4285	Finger Splint
3280	Plastic finger splint