



Declaration of Conformity

Product Designation: Support, Arm

UMDNS- Code: 13-862

Issue Date: May 26, 2021

Valid Date: May 26, 2022

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: Not yet published.

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 ANNEX II (Technical documentation) & ANNEX III (Technical documentation on post-market surveillance)

Risk Classification of the Product: Class I Rule: MDR (EU) 2017745, Annex VIII, Section 4, 4.1, Rule 1 "All non-invasive devices are classified as class I."

Applied Harmonized Standards: EN ISO9001:2015, EN ISO13485:2016, EN1041:2008,
EN ISO14971:2012, EN ISO 15223-1:2016,
EN ISO10993-5:2009, EN ISO 22523:2006

Intended purpose: The support, arm relieves pain and alleviates strains, sprains, and overstretch injuries. It provides ideal compression and retains heat to alleviate soft tissue adhesions.

May 26, 2021/Seattle

Date/Place

Jackson Chiang

Mr. Jackson Chiang
President



Attachment 1

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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
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
2385	Elbow Support
RE200	Elbow Support
RE300	Tennis Elbow Strap

Wrist

Reference number	Product Trade name
1081	Wrist Wrap
1083	Wrist Wrap
1084	Wrist/Thumb Support
1188	Wrist/Thumb Support
1281	Wrist Wrap
2081	Wrist Wrap
2083	Wrist Wrap
2084	Palm Brace
2181	Wrist Wrap
2184	Wrist Thumb Brace
2281	Wrist Support
2583	Wrist Support
2586	Nano Wrist Support
2681	Biomagnetic Wrist Support
2980	Wrist Support
2383	Thumb Loop Wristband
2384	Palmar Thumb Support
RH100	Wrist Wrap
RH101	Wrist Wrap