



Declaration of Conformity

Product Designation: Splints, Hand/Finger

Issue Date: May 26, 2021

UMDNS- Code: 16-210

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 splints, hand/finger soothe pain and alleviate strains, sprains, and overstretch injuries. The splints stabilize injured areas and prevent further injury.

May 26, 2021/Seattle

Jackson Chiang

Date/Place

Mr. Jackson Chiang
President



Attachment 1

Product Designation: Splints, Hand/Finger
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Wrist

Reference number	Product Trade name
1082	Wrist Splint
1088	Wrist/Thumb Support
1089	Wrist/Thumb Support
1180	Wrist/Thumb Support
1184	Wrist/Thumb Support
1288	Wrist/ Thumb Support
1289	Wrist/Thumb Support
1389	Wrist/Thumb Support
2082	Wrist Splint Brace
2182	Wrist Splint W/Elastic Strap
2288	Wrist Splint With Elastic Strap
2984	Wrist Stabilizer
3088	Thumb Orthosis
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
2387	Wrist Stabilizer
2388	Deluxe Wrist Stabilizer
2389	Thumb Stabilizer
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