



Declaration of Conformity

EMDN CND Code : Y061203

Issue Date: Mar. 02, 2022

EMDN CND Description: Orthoses, foot (including insoles and inserts)

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: 8402706CL107L7

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 relieve pain and fatigue in the feet, legs, and lower back. They redistribute bodyweight pressure equally to all parts of the feet.

Mar. 02, 2022/ Seattle

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Date/Place


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Jackson Chiang
President



Attachment 1

EMDN CND Code : Y061203

EMDN CND Description: Orthoses, foot (including insoles and inserts)

Reference number	Product Trade name
5001	Cushion Air Insoles
5002	Massage Air Insoles
5003	Arch Insoles
5010	Arch Support Insoles
5011	Diabetic Insoles
5015	Eco-friendly Comfort Insoles
5016	Eco-friendly Orthotic Insoles
5017	Eco-friendly Slim Insoles
5401	Silicone Elastmax Insoles
5404	Silicone Insoles (3/4 length)
5405	Metatarsal Insoles
5406	Tender Silicone Insoles
5407	Silicone Elastmax Insoles
5408	Soft Step Silicone Insoles
5409	Silicone Insoles
5410	Step Easy Full Length Insoles
5451	Silicone Heel Cushions
5452	Heel Cushions
5453	Heel Cups
5454	Silicone Heel Cushions
5459	Arch Pads
5460	Heel Pads With Removable Pads
5463	Heel Pads
5464	U-shape Heel Spur Pads
5466	Plantar Fasciitis Reliever
5501	Bioceramic Insoles
5601	Magnetic Insoles
5707	Waffle Support Gel Insoles
5708	Waffle Comfort Gel Insoles
5011DM	Cushion Foam Insoles
5015DM	Antibacterial Dual Density Foam insoles
5401DM	Dual Density Silicone Insoles
5454DM	Silicone Heel Cup
6020	Foam Oval Corn Pad
6021	Foam Retractors



6022	Multi Toe Combs
6070	Foam Protective Pad
6071	Heel Protectors
6080	Foam Ball of Foot Pads
6081	Raised Metatarsal Pads
6420	Hallux Straightener
6421	Gel Toe Separators
6422	Retractor
6423	Hallux Straightener
6424	Retractor
6425	Toe Crests
6426	5th Toe Bunion Protector
6440	Hallux Valgus Protector
6441	Toe Crest
6442	Metatarsal Pads
6443	Hallux Valgus Protector
6472	Protective Pads
6474	Oval Corn Pads
6480	Metatarsal Pad
6481	Metatarsal Pad
6700	Gel Digital Pads
6702	Gel Elastic Sleeves (half coated)
6703	Tubular Pad (long)
6704	Gel Toe Caps
6705	Gel Cushion
6706	Gel Toe Sleeves
6720	Gel Digital Rings
6723	Gel Toe Combs
6740	Gel Bunion Cushion
6741	Gel Bunion Sleeve
6750	Arch Pad
6760	Sandal Toe Separator
6761	Sandal Ball Cushions
6770	Achilles Protection Pad
6780	Gel Metatarsal Bandage
6781	Ball of Foot Gel Pad
6782	Metatarsal Foot Pads
6783	Gel Metatarsal Pads
6790	Gel Heel Sock
6791	Malleolar Sleeve
6792	Heel Protectors
6920	Hallux Valgus Night Strap
6950	Arch Bandage
6021DM	Foam Toe Separators
6090DM	Pressure Relief Foam Cushion