



## Declaration of Conformity

EMDN CND Code : Y060399

Issue Date: Mar. 02, 2022

EMDN CND Description: Spine 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: 8402706CL104KZ

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 : Y060399

EMDN CND Description: Spine orthoses – other

Rib

Reference number	Product Trade name
4073	Rib Belt
4074	Rib Belt

Waist

Reference number	Product Trade name
1060	Waist Belt
1063	Back Support
1064	Sacro Lumbar Support
1660	Magnetic Back Support
2060	Abdominal Binder
2061	Sacral Cinch Belt
2062	Maternity Back Support
2064	Lumbar Sacro Support
2065	Sacro Lumbar Support
2068	Sacro Lumbar Support
2160	Abdominal Binder
2162	Abdominal Binder
2163	Sacro Lumbar Support
2164	Sacro Lumbar Support
2166	Spinal Brace
2167	Sacro Lumbar Support With Removable Pad
2168	Sacro Lumbar Support
2169	Industrial Back Support
2260	Abdominal Support
2262	Sacro Belt
2263	Sacro Lumbar Support With Pad
2264	Sacro Lumbar Support
2265	Sacro Lumbar Support
2267	Sacro Lumbar Support
2268	Mesh Abdominal Binder
2350	Lumbar Protector
2352	Adjustable Back Support
2355	Pelvic Stabilizing Belt
2356	Posture Brace
2360	Abdominal Support



2366	Lumbar Support
2367	Pro Lumbar Support
2368	Deluxe Lumbar Support
2369	Deluxe Pro Lumbar Support
2460	Silicone Abdominal Belt
2668	Magnetic Waist Belt
2950	Back Support
2951	Lumbar Dual-Secure
2952	Tri-fend Lumbar Secure
2953	Spinal Adjustor
2968	Lumbar Secure
3462	Core Stability Support
4062	Maternity Belt
RW500	Back Brace
RW501	Back Stabilizer