



## Declaration of Conformity

EMDN CND Code :V080399

Issue Date: Mar. 01, 2022

EMDN CND Description: Medical cushions - 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: 8402706CL108L9

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 62366:2008,  
ISO 10993-10:2021, ISO 9001:2015

Intended purpose: The devices relieve tension and muscle stiffness by evenly distributing body weight and pressure. They also alleviate discomfort associated with improper sitting or sleeping position.

Mar. 02, 2022/ Seattle

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Date/Place

  
Jackson Chiang  
President



Attachment 1

EMDN CND Code :V080399

EMDN CND Description: Medical cushions – other

Reference number	Product Trade name
OF10141	MemoPillow
OF10142	Baby MemoMax Pillow
OF10161	MemoPillow
OF10162	Traveler MemoMax Pillow
OF10181	MemoPillow
OF10182	Traveler MemoMax Pillow
OF20061	Bodymate MemoPillow
OF30041	Universal MemoPillow
OF20041	Backmate MemoCushion
OF40541	Wheelmate MemoCushion
OF50541	Hipmate MemoCushion