Declaration of Conformity

EMDN Code : Y061209
EMDN Description: Knee orthoses

Issue Date: Dec. 17, 2024
Valid Date: Dec. 31, 2026

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: Ernst-Heckel-Straße 7, D-66386 St. Ingbert Germany Single registration number (SRN): DE-AR-000000085

The basic UDI-DI: 08402706CL1154W

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 ISO14971:2019, EN ISO 15223-1:2021, 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 OPPO GENU S is a medical device. It is an orthosis for stabilizing and guiding the knee joint.

Dec. 17, 2024/ Seattle
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Date/Place

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Jackson Chiang
President

Attachment 1

EMDN Code : Y061209

EMDN Description: Knee orthoses

Reference number	Product Trade name
2936	OPPO GENU S