Declaration of Conformity

Product Designation: Trusses, Hernia
UMDNS- Code: 14-169

Issue Date: May 26, 2021
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 trusses, hernia helps resolve inguinal hernias. It targets the specific location of a hernia and keeps protruding tissue in place to relieve discomfort.

May 26, 2021/Seattle
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Date/Place

Jackson Chiang
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Mr. Jackson Chiang
President

Attachment 1

Product Designation: Trusses, Hernia
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Reference number	Product Trade name
2049	Hernia Truss Double-Sided
2149	Hernia Truss Single-Sided
2249	Hernia Truss with Removable Pad