Declaration of Conformity

Product Designation: Support
UMDNS- Code: 13-858

Issue Date: Oct. 12, 2018
Valid Date: Oct. 12, 2022

Model No's: Shoulder - 1072, 2072, 2172, 2970, 4072, 4172
Knee - 1021, 1022, 1023, 1024, 1028, 1029, 1030, 1031, 1032, 1033, 1034, 1036, 1038, 1124, 1125, 1130, 1132, 1136, 1221, 1230, 1231, 1232, 1237, 1429, 2021, 2022, 2029, 2030, 2031, 2032, 2034, 2037, 2038, 2120, 2123, 2133, 2137, 2222, 2233, 2420, 2430, 2438, 2438H, 2520, 2523, 2529, 2620, 2621, 2920, 2921, 2923, 2924, 2930, 3131, 3132, 4024, 4030, 4039, 4130, 4139, 4239, 3133, 4020, 4021, 2323, 2320, 2321, 2330, 2331
Ankle - 1001, 1003, 1004, 1008, 1009, 1103, 1108, 1109, 1201, 1408, 1409, 2001, 2003, 2004, 2011, 2101, 2103, 2201, 2204, 2401, 2409, 2502, 2504, 2507, 2509, 2601, 2900, 2902, 2903, 2909, 3007, 3008, 3009, 3107, 3108, 3109, 3208, 3209, 4001, 4006, 4007, 4009, 4106, 4109, 4206, 2302
Shin - 1010, 2010, 2420
Thigh - 1040, 2040
Clavical - 2075, 2175, 2275, 4075
Rib - 4073, 4074

We herewith declare that the products listed above are in compliance with the requirements set out in the Council Directive on the harmonization of the Laws of the Member States concerning Medical Device Directive 93/42/EEC.

Conformity Assessment Procedure: MDD 93/42/EEC Annex VII

Classification of the Product: Class I Rule: MDD 93/42/EEC Annex IX Rule 1

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

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

Oct. 12th, 2018
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Date

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Mr. Jackson Chiang
President

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Model No's: see page 1 of this Declaration of Conformity

EU Authorized Representative: **MT Promedt Consulting GmbH**
Altenhofstrasse 80
D-66386 St. Ingbert
Germany

MT Promedt Consulting GmbH (MTPC) has taken over the function and responsibilities of an European Authorized Representative of OPPO Medical Inc. in accordance to the requirements of the MDD 93/42/EEC.
The manufacturer has provided MTPC with the Technical Documentation.
The necessary notification of the above mentioned products has been performed. The products are registered under the Reg.-Nr.: DE/CA70/40838/0048120