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| tenortho | DECLARATION OF CONFORMITY UE<br>**«ORTHOPAEDIC BRACES»** | Rev.0 may 2021 |

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|---|---|
| **Manufacturer** | TENORTHO S.R.L. |
| **Single Registration Number** | N.A. |
| **Address** | Via Trento e Trieste, 100, 20853 Biassono MB |
| **Basic UDI-DI** | 805571519820049M8 |
| **Medical Device** | **MODULAR DORSO-LUMBAR CORSET WITH REVERSE SHOULDER STRAPS** |

**Product identification:** **82-0049 – DONJOY OSTEOSTRAP**

**Destination of use:** Therapeutic and not invasive Medical Devices, capable to correct postural problems

Classification in accordance of Annex VIII Class I, rule 1
(Regulation (EU) 745/2017)

The manufacturer declares, under its sole responsibility, that the product complies requirements of (EU) 745/2017

**Standard conformity**:

| ***CODE*** | **DESCRIPTION** |
|---|---|
| *UNI EN ISO 14971: 2020* | Medical Device – Application of risk management to medical devices |
| UNI EN ISO 13485: 2016 | Medical Devices. Quality Management Systems. Requirements for regulatory purposes. |
| UNI CEI EN ISO 15223-1: 2017 | Medical Devices: Symbols to be used in medical devices labels, labelling and information to be supplied – Part 1 General requirements. |
| *MEDDEV 2.7.1/1 rev.4–06-2016* | Clinical evaluation: Guide for manufacturers and notified bodies |
| *MEDDEV 2.12-1* | Guidelines on medical devices surveillance system. |
| UNI EN ISO 10993-1:2010 | Biological Evaluation of medical devices – Part1: Evaluation and trials in risk management process. |
| UNI CEI EN 1041:2013 | Information provided by manufacturer of medical devices |
| UNI EN 22675:2006 | Prosthetics - Testing of ankle-foot devices and foot units - Requirements and test methods |

Place, date
Biassono, 17th June 2021

Signature (Legal Representative)