

Warsaw, 25.05.2021

## EU DECLARATION OF CONFORMITY MEDICAL DEVICE

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acting as Manufacturer registered in Eudamed, SRN number: PL-MF-000001583, according to Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017, herein declare that medical devices:

### LUMBO-SACRAL ORTHOSIS: AT04502, AT04504

The Basic UDI-DI: 59015714AT0450238, 59015714AT045043C

have been classified as medical device class I, rule 1.

Intended purpose: lumbo-sacral spine orthoses designed for maximum restriction of movements and/or total immobilization (i.e., motion control) of the lumbar and sacral segments of the spine

We herein declare that the medical devices are in conformity with Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017. The assessment of conformity has been proceeded in compliance with the requirements of the above Regulation.

#### Applied standards:

PN-EN ISO 9001 (current edition)  
PN-EN ISO 13485 (current edition)  
PN-EN ISO 15223 (current edition)  
PN-EN ISO 14971 (current edition)  
PN-EN ISO 10993 (current edition)

The EU declaration of conformity is issued under the sole responsibility of the Manufacturer.

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Andrzej Tarnkowski



co-owner  
independent representation of the company  
based on the Company Register

