

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:

ELASTIC ANKLE ORTHOSIS (POLYESTER) : AT53015

The Basic UDI-DI: not issued

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

Intended purpose: ankle orthosis is designed for people who have had joint instability or twisting. The brace gives you a speedy recovery. The brace protects the ankle after the injury as well as during sports

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

