

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:

**OTRHOPAEDIC INSOLES, MADE OF LEATHER AT53501**

**OTRHOPAEDIC INSOLES, MADE OF LEATHER AT53502**

**OTRHOPAEDIC INSOLES, MADE OF LEATHER AT53503**

**OTRHOPAEDIC INSOLES, MADE OF LEATHER AT53504**

**HEEL PADS, MADE OF LEATHER AT53505**

**HEEL PADS, MADE OF LEATHER AT53506**

**HEEL PADS, MADE OF LEATHER AT53507**

**HEEL PADS, MADE OF LEATHER AT53508**

**HEEL PADS, MADE OF LEATHER AT53509**

**HEEL PADS, MADE OF LEATHER AT53510**

**HEEL PADS, MADE OF LEATHER AT53511**

**HEEL PADS, MADE OF LEATHER AT53512**

**LEATHER STOPPERS AT53513**

**SEMI-INSOLES MADE OF LEATHER AT53514**

The Basic UDI-DI: not issued

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

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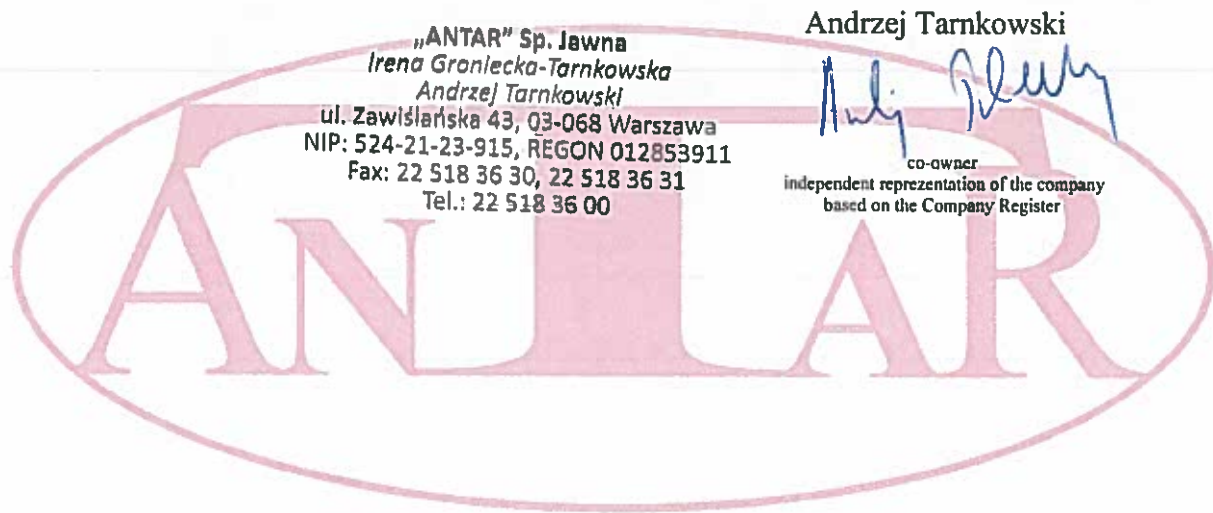
Intended purpose: insoles are designed to manage flat foot - longitudinal or crosswise, by tracing foot arch

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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