



## EU DECLARATION OF CONFORMITY

*Irena Groniecka-Tarnkowska, Andrzej Tarnkowski "ANTAR" General Partnership  
ul. Zawisłańska 43; 03-068 Warsaw, Poland  
SRN: PL-MF-000001583*

We hereby declare, under our sole responsibility, that the medical device covered by this declaration of conformity complies with all applicable requirements of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices (MDR).

**MEDICAL DEVICE: FOREFOOT OFFLOADING ORTHOSIS: AT53102**

Basic UDI-DI Code: 59015714AT5310244

The device has been classified in accordance with Annex VIII of the MDR as a **Class I medical device, Rule**

**Intended purpose:** The forefoot offloading orthosis is intended for temporary use to stabilize and protect the forefoot following surgical procedures. Its design shifts pressure to the heel, supporting the healing process of wounds, ulcers, and injuries in the anterior part of the foot. The adjustable fastening system allows the product to accommodate feet with dressings, bandages, or swelling.

The conformity assessment was carried out according to Annex II and III of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, with the application of the following standards:

PN-EN ISO 15223-1:2022

PN-EN 20417:2021

PN-EN ISO 14971:2020

PN-EN ISO 13485:2016

PN-EN ISO 10993-1:2021

PN-EN 62366-1:2015-07/A1:2021

The EU Declaration of Conformity has been issued under the sole responsibility of the manufacturer.

Andrzej Tarnkowski

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



Warsaw, 21.11.2025