



EU DECLARATION OF CONFORMITY

ANTAR MEDICAL Limited Liability Company
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: 59015714AT5310244

The device has been classified in accordance with Annex VIII of the MDR as a **Class I medical device, Rule 1**

Intended purpose: the forefoot off-loading orthosis is intended for temporary use to relieve and protect the forefoot after surgical procedures and to maintain mobility as part of disability compensation. The design shifts pressure to the heel, thereby supporting the healing process of wounds, ulcers, and injuries in the forefoot area. The adjustable fastening system allows adaptation to 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.



Version 4_2.2026

Andrzej Tarnkowski

co-owner

independent representation of the company
based on the Company Register


Warsaw, 25.02.2026