



Warsaw, 22.05.2024

## EU DECLARATION OF CONFORMITY MEDICAL DEVICE

*Irena Groniecka - Tarnkowska, Andrzej Tarnkowski „ANTAR” Spółka Jawna  
ul. Zawisłańska 43  
03-068 Warszawa*

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:

### **WALKER: AT51006C**

The Basic UDI-DI: 59015714AT51006C4R  
have been classified as medical device class I, rule 1.

Intended purpose: The walker is intended for elderly individuals, patients recovering from orthopedic surgeries, people with balance disorders, as well as those with chronic conditions that limit their ability to move independently. It assists in daily activities such as walking, getting up from a chair, moving around the house and outdoors, providing support and stability, which reduces the risk of falls and injuries. It is equipped with a walking cane attached to the walker, which can be detached and used by the user as additional support, especially when getting up from a seat or moving through narrow spaces where using the entire walker may be difficult.

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: 2015  
PN-EN ISO 13485: 2016  
PN-EN ISO 15223-1: 2021  
PN-EN ISO 14971: 2020  
PN-EN ISO 10993-1: 2021

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

Andrzej Tarnkowski

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

