

Warsaw, 25.05.2021

## 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:

### ROM HIP JOINT ORTHOSIS: AT53033

The Basic UDI-DI: not issued

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

Intended purpose: hip lower-limb orthoses supports treatment and accelerates rehabilitation. It is used primarily in more serious injuries or advanced degenerative changes. It is most often used after surgery, e.g. hip plasty or replacement. It is also used in the process of verticalization, learning to walk after surgery or using the endoprosthesis

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.

„ANTAR” Sp. Jawna  
Irena Groniecka-Tarnkowska  
Andrzej Tarnkowski  
ul. Zawisłańska 43, 03-068 Warszawa  
NIP: 524-21-23-915, REGON 012853911  
Fax: 22 518 36 30, 22 518 36 31  
Tel.: 22 518 36 00

Andrzej Tarnkowski



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

