

Warsaw, 25.05.2021

## EU DECLARATION OF CONFORMITY MEDICAL DEVICE

*Irena Groniecka - Tarnkowska, Andrzej Tarnkowski „ANTAR” Spółka Jawna  
ul. Zawiślańska 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:

### WRIST ORTHOSIS: AT53031, AT53032

The Basic UDI-DI: 59015714AT5303146, 59015714AT5303248

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

Intended purpose: wrist brace is a type of stabilizer that, like the cast, holds the joint in one fixed position.

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.

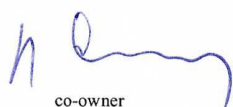
#### Applied standards:

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.

Andrzej Tarnkowski

„ANTAR” Sp. Jawna  
Irena Groniecka-Tarnkowska  
Andrzej Tarnkowski  
ul. Zawiślańska 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

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

