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EU DECLARATION OF CONFORMITY

Irena Groniecka-Tarnkowska, Andrzej Tarnkowski "ANTAR" General Partnership
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SRN: PL-MF-000001583

We hereby declare, under our sole responsibility, that the product covered by this declaration of conformity complies with the requirements of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 [MDR].]

ELBOW CRUTCH: AT51130_AT51131

The Basic UDI-DI: 59015714AT511303T, 59015714AT511313V

The device has been classified in accordance with Annex VIII of MDR as Class I, Rule 1.

Intended purpose: Elbow crutches are designed for people, who cannot stay on a leg because of its injury. User rests on crutches, moves the crutches and makes a step without necessity to stay on the injuried leg.

The conformity assessment was carried out according to Annex II + 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 ISO 10993-10:2015
PN-EN 62366-1:2015-07/A1:2021

version 1_11.2024

Andrzej Tarnkowski
co-owner
independent reprezentation of the company
based on the Company Register

Warsaw, 26.11.2024

CE