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EU DECLARATION OF CONFORMITY

Irena Groniecka-Tarnkowska, Andrzej Tarnkowski "ANTAR" General Partnership
ul. Zawiślańska 43; 03-068 Warsaw, Poland
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].]

REHABILITATION BALL AT51400, AT51401, AT51402, AT51403, AT51404, AT51405, AT51415, AT51417, AT51418, AT51419, AT51420, AT51430

The Basic UDI-DI: 59015714AT514003Z, 59015714AT5140143, 59015714AT5140245, 59015714AT5140347, 59015714AT5140449, 59015714AT514054B, 59015714AT514154E, 59015714AT514174J, 59015714AT514184L, 59015714AT514194N, 59015714AT5142047, 59015714AT514304A

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

Intended purpose: rehabilitation balls are intended for exercise and massage. They are used during exercise of muscles, tendons and joints, especially during rehabilitation, as well as for body massage.

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

version 2_11.2024

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

Warsaw, 16.11.2024

CE