



Warsaw, 20.10.2023

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:

SHOULDER ABDUCTION ORTHOSIS: AT53074

The Basic UDI-DI: 59015714AT530744Q

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

Intended purpose: The shoulder abduction brace allows the upper limb to be immobilized in abduction. Soft support with an anatomical profile ensures comfort and relieves the shoulder joint. Recommended after shoulder surgery.

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

