



EU DECLARATION OF CONFORMITY

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SRN: PL-MF-000001583*

We hereby declare, under our sole responsibility, that the medical device covered by this declaration of conformity complies with all applicable requirements of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices (MDR).

MEDICAL DEVICE: ORTHOPEDIC COLLAR: AT53070, AT53071

Basic UDI-DI Code: 59015714AT530704G, 59015714AT530714J

The device has been classified in accordance with Annex VIII of the MDR as a **Class I medical device, Rule 1**

Intended purpose: The AT53070 orthopedic collar is a collar of foam with a built-in internal stiffening insert and is intended to stabilize the cervical spine. The AT53071 orthopedic collar is a rigid collar. It is intended for complete fusion of cervical spine. Light and X-ray permeable. Supports the head both from the back and from the front. Provides complete stabilization of the cervical spine. Suitable for long-term use. It has a hole for tracheostomy.

The conformity assessment was carried out according to Annex II and 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

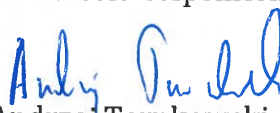
PN-EN ISO 10993-5:2009

PN-EN ISO 10993-10:2015

PN-EN 62366-1:2015-07/A1:2021

The EU Declaration of Conformity has been issued under the sole responsibility of the manufacturer.




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

Warsaw, 29.28.2025