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## EU DECLARATION OF CONFORMITY MEDICAL DEVICE

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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:

**SPINAL ORTHOSIS: AT53052, AT53053, AT53054**

The Basic UDI-DI:

AT53052: 59015714AT530524E  
AT53053: 59015714AT530534G  
AT53054: 59015714AT530544J

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

Intended purpose: The spine brace is designed to provide support, protecting the structure of the spine and ensuring proper body posture while allowing normal activity.

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.

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Andrzej Tarnkowski

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

CE

