

## EU DECLARATION OF CONFORMITY

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We hereby declare, under our sole responsibility, that this declaration of conformity has been issued in accordance with Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices (MDR), and that the relevant requirements of the Regulation have been fulfilled.

### Medical Device:

FINGER SPLINT ORTHOSIS: AT53103	Basic UDI-DI: 59015714AT5310346
FINGER SPLINT ORTHOSIS: AT53104	Basic UDI-DI: 59015714AT5310448
FINGER SPLINT ORTHOSIS: AT53105	Basic UDI-DI: 59015714AT531054A
FINGER SPLINT ORTHOSIS: AT53106	Basic UDI-DI: 59015714AT531064C

The devices have been classified according to Annex VIII of the MDR as Class I, based on Rule 1.

Intended use: Finger splints and orthoses are used to immobilize fingers in cases of fractures or dislocations, as well as in injuries of the interphalangeal joints and fingertip injuries. The soft padding prevents excessive sweating and enhances comfort during prolonged use.

Conformity assessment has been carried out according to Annex II and III of Regulation (EU) 2017/745.

The following standards have been applied to demonstrate compliance:

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



Andrzej Tarnkowski

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



Warsaw, 24.04.2025