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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:

SOFT CERVICAL COLLAR: AT53029

The Basic UDI-DI: not issued

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

Intended purpose: The soft orthopedic collar is the type of cervical orthosis, use to stabilize the upper spine by temporary (total or partial) immobilization. The anatomical shape and the material of which the collar is made allow for effective rehabilitation and relatively normal functioning of the patient, who can perform daily activities without too much difficulty

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 (current edition)
PN-EN ISO 13485 (current edition)
PN-EN ISO 15223 (current edition)
PN-EN ISO 14971 (current edition)
PN-EN ISO 10993 (current edition)

The EU declaration of conformity is issued under the sole responsibility of the Manufacturer.

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

