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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:

ARM SLING: AT04003_AT04005_AT04006

The Basic UDI-DI: 59015714AT040032H_59015714AT040052M_59015714AT04006AP
have been classified as medical device class I, rule 1.

Intended purpose: arm sling ensures immobilization and maintain limb for mild sprains shoulder. It is used in post-operative conditions, dislocations, sprains. Supporting the shoulder, the weight of the whole is transferred to the back.

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

