DECLARATION OF CONFORMITY

No. 62/D/EN/2

COMPANY
REH4MAT Sławomir Wroński

DECLARES

that product:

CERVICAL COLLAR

MODEL: CERVICAL COLLAR AM-KOL-01; CERVICAL COLLAR AM-KOL-02; CERVICAL COLLAR AM-KOL-03; CERVICAL COLLAR AM-KOL-04; CERVICAL COLLAR AM-KOL-05; CERVICAL COLLAR 4ARMY-KOL-01; CERVICAL COLLAR 4ARMY-KOL-02; CERVICAL COLLAR 4ARMY-KOL-03; CERVICAL COLLAR 4ARMY-KOL-04; CERVICAL COLLAR 4ARMY-KOL-05; CERVICAL COLLAR 4ARMY-KOL-06


The product meets the requirements of the harmonized standards:

PN-EN 1041+A1:2013-12 Information supplied by the manufacturer of medical devices
PN-EN 12182:2012 Assistive products for persons with disability. General requirements and test methods
PN-EN ISO 13485:2016 Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes
PN-EN ISO 14971:2012 Medical devices. Application of risk management to medical device
PN-EN ISO 15223-1:2017-02 Medical devices Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements

THIS DECLARATION HAS BEEN ISSUED ON THE RESPONSIBILITY OF THE COMPANY REH4MAT Sławomir Wroński, 36-060 Głogów Małopolski, ul. Piaski 47, POLAND

Country of origin: POLAND

Głogów Małopolski, 04.03.2019

Company owner
Sławomir Wroński