EU DECLARATION OF CONFORMITY

CE

SIGVARIS GROUP

MANUFACTURER:

SIGVARIS S.A.
ul. Mazowiecka 11 lok. 49
PL 00-052 Warszawa

Single registration number (SRN):
PL-MF-000004824

declares under his sole responsibility that the medical device:

PT 0302 Elastic ankle support

list of manufacturing types/models/versions specified in Annex 1

Basic code UDI-DI: 5906699PT0302YZ

is in compliance with the applicable requirements of REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices.

In accordance with Annex VIII to Regulation 2017/745, the product is classified as a class I medical device in line with the Rule 1.

To demonstrate the safety and performance of the medical device, the following standards were used to assess the conformity:

EN ISO 13485:2016
Medical devices – Quality management systems – Requirements for regulatory purposes

EN 1041:2008
Information supplied by the manufacturer of medical devices

EN ISO 15223-1:2016
Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements

EN ISO 14971:2012
Medical devices – Application of risk management to medical devices

EN 62366:2008
Medical devices – Application of usability engineering to medical devices

EN ISO 10993-1:2009
Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process

Revision: 2

Place and date of issue:

Warszawa, 24.11.2021

Approved by:

Magdalena Kwiatkowska – President of the Management Board
Bartosz Uchman – Member of the Management Board

Stamp and signature:

SIGVARIS S.A.
Magdalena Kwiatkowska
Prezes Zarządu

SIGVARIS S.A.
Bartosz Uchman
Członek Zarządu