CE

MD Medical Device

EU DECLARATION OF CONFORMITY

Manufacturer:

Vitberg Sikora Jacek
ul. Borelowskiego 29
33-300 Nowy Sącz
POLAND, EU
SRN PL-MF-000010936

I declare, under my sole responsibility, the medical device:

RS2 Positioning Wedge 1

RS2 Positioning Wedge 2

RS2 Positioning Wedge 3

RS2 Armrests

Med Home Wedge 1

Med Home Wedge 2

Basic UDI-DI 590470340V2MNCM

In accordance with REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL (EU) 2017/745 of April 5, 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/ EEC, Annex VIII is classified, as Class I under Rule 1.

The device meets, the applicable requirements of REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL (EU) 2017/745 of April 5, 2017 on medical devices.

The list of standards and legal regulations used for the conformity assessment can be found in the technical documentation. The market release is carried out based on the provisions of the quality control protocol in the TD5 technical documentation [TD5].

Jacek Sikora
CEO

Vitberg

Nowy Sącz, Poland, EU 20.12.2022