CE 0197

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:

Vitberg Recovery System
(other names Vitberg, Base Device)
Models, types: RS, RS2, Med Home

Basic UDI-DI 590470340V2RSDE

Product qualified as:

MD 1108 Active rehabilitation devices and active prostheses

Description: Device for medical vibrotherapy and active physiotherapy. Recommended for post-traumatic rehabilitation, strengthening the locomotor system, alleviating the symptoms of diseases (including pain), improving metabolism, relaxing tissues, stimulating the circulatory system, facilitating movement, relieving joints, relaxing and protecting against injuries. Performing exercises during vibrotherapy increases its effectiveness. It is recommended to perform corrective, strengthening, breathing, loosening and relaxation exercises during the treatments. You can also use guided and self-assisted exercises, isometric exercises, active, passive and active-passive limbs, as well as synergistic exercises, which help to effectively activate individual muscle groups through functional connections.

In accordance with the Regulation of the Minister of Health of November 5, 2010 on the methods of medical device classification (Journal of Laws of 2010, no. 215, item 1416) is classified as class IIa under rule 9.

The device meets the applicable requirements of the Medical Devices Act of April 7, 2022 (Journal of Laws of 2022, item 974) and Directive 93/42/EEC.

The conformity assessment procedure conducted in accordance with the Annex 2.3 of the Regulation of the Minister of Health of February 17, 2016 on essential requirements and conformity assessment procedures of medical devices as amended (Journal of Laws of 2016, item 211). The list of standards and legal regulations used for 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 TD2.

The Notified Body participating in the conformity assessment:

TÜV Rheinland LGA Products GmbH
Tillystraße 2
90431 Nürnberg
Germany

Jacek Sikora
CEO

Nowy Sącz, Poland, EU 20.12.2022

Vitberg