EU DECLARATION OF CONFORMITY

manufacturer: ZARYS International Group sp. z o.o. sp.k.
address: ul. Pod Borem 18, 41-808 Zabrze, Poland
contact: tel. +48 32 271 69 91, fax +48 32 274 72 84,
e-mail: zarys@zarys.pl, website: www.zarys.com
SRN: PL-MF-000000410

We declare under our sole responsibility that a medical device:

elastoBAND FLEX
elastic supporting bandage, woven, non-sterile

sizes*: from 8cm x 4m to 15cm x 5m
(*detailed list of products covered by this declaration is available in document TD-45-I.1.1.b-1.2– Identification – Annex 1, batch code - release document DZDO-01– Annex 2)

classification:

- class I, rule 1 (in accordance with Annex VIII of Regulation (EU) 2017/745)

Basic UDI-DI: 59079968M03040201HJ

intended purpose: Device intended for holding dressings and for supporting and compressing body parts to treat sprains and strains, lymphoedema and to strengthen skin layers after surgery.

is in conformity with Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.

The device described above meets all applicable provisions of the Annex I of Regulation (EU) 2017/745. Conformity assessment procedure has been performed in accordance with Article 52 (7).

The medical device covered by the present declaration of conformity complies with european standards:

EN ISO 13485:2016, EN ISO 14971:2019, EN 62366-1:2015/A1:2020, EN ISO 15223-1:2016, EN 1041:2008+A1:2013, EN ISO 10993-1:2020, EN ISO 10993-5:2009, EN ISO 10993-10:2013, EN ISO 11737-1:2018.

Digitally signed by Palii Nina
Date: 2021.09.14 16:44:37 EEST
Reason: MoldSign Signature
Location: Moldova

place and date of issue: Zabrze, 1.07.2021
name: Wioletta Gajda
position: Product Manager

PRODUCT MANAGER
ZARYS International Group sp. z o.o. sp.k.
Wioletta Gajda

.....
signature
(on behalf of the President of the General Partner's Management Board)

CE