

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 6cm 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. The list of supervised standards is included in document TD-45-I.4.c-1 - Annex 3.

place and date of issue: Zabrze, 1.09.2022
name: Wioletta Wójcik
position: Product Manager

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

Handwritten signature of Wioletta Wójcik in blue ink, with the name "Wioletta Wójcik" printed below it.

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

