

EU DECLARATION OF CONFORMITY



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SRN: PL-MF-000000410

We declare under our sole responsibility that a medical device:

elastopor E
dressing tape, non-woven, self-adhesive, non-sterile

sizes*: from 2,5cm x 10m to 30cm x 10m

(*detailed list of products covered by this declaration is available in document TD-06-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: 59079968M050199FG

intended purpose: Device intended for stabilisation, protection and fixation of drains, catheters, medical tubes as well as primary dressings (contact), non-adhesive, applied directly to wounds and skin damages.

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-06-I.4.c-1 - Annex 3.

place and date of issue: Zabrze, 1.12.2021
name: Wioletta Gajda
position: Product Manager

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

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

