EU DECLARATION OF CONFORMITY



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SRN: PL-MF-000000410

We declare under our sole responsibility that a medical device:

elastoNET

elastic tubular net bandage, non-sterile

sizes*: from 1 to 14 length*: 1m; 10m

(*detailed list of products covered by this declaration is available in document TD-45-I.1.1.b-2.1– 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: 59079968M03030103H6

intended purpose: Device intended for fixing and supporting all kinds of non-adhesive dressings on the patient's body, replacing traditional bandages, especially in places difficult to reach.

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-2 - Annex 3.

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

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

