# EU DECLARATION OF CONFORMITY


manufacturer: ZARYS International Group sp. z o.o. sp.k.
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SRN: PL-MF-000000410


We declare under our sole responsibility that a medical device:

non-sterile adhesive tapes on a roll

models*: FILMplast adhesive PE tape;
PLASTIplast adhesive fabric tape;
POREplast adhesive perforated non-woven tape;
SENSIplast adhesive fabric tape;
SILKplast adhesive silk tape;
SOFTplast adhesive non-woven tape

sizes*: from 1,25cm x 5m to 5cm x 9,14m
(*detailed list of products covered by this declaration is available in document TD-06-I.1.1.b-5– 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: 59079968M050101E5

intended purpose: Device intended for stabilisation, protection and fixation of drains, catheters, medical tubes not requiring specialised fixation at their place of application 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-5 Annex 3.

Digitally signed by Granaci Boris
Date: 2025.06.08 12:47:57 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

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)

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