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:

VOMIT BAG

colours*: blue; red; white

(*detailed list of products covered by this declaration is available in document TD-58-I.1.1.b-1– Identification – Annex 1, batch code - certificate of analysis of production batch DZDO-01– Annex 2)

classification:

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

Basic UDI-DI: 59079968G995K

intended purpose: Disposable device intended for collection of gastric contents during patient vomiting to observe the nature of the secretions for further diagnostic action.

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-58-I.4.c-1 - Annex 3.

place and date of issue: Zabrze, 29.11.2023
name: Bożena Smolnik
position: Product Manager

Digitally signed by Granaci Boris
Date: 2025.06.19 11:56:29 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

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

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

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