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:

BETAtex
Colonoscopy boxers, non-woven, non-sterile*

(*detailed list of products covered by this declaration is available in document TD-30-I.1.1.b-5.2 – 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: **59079968T0306RD**

intended purpose: Single-use medical device intended for use by the patient during surgical interventions and invasive diagnostic examinations, used as a barrier to minimise the transfer of particles such as dust, exfoliated epidermis, which are carriers of pathogens residing in the patient's natural flora, to the surgical wound or inside the patient's body, thereby reducing the risk of wound infection and preventing disease.

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-30-I.4.c-5 - Annex 3.

place and date of issue: Zabrze, 4.11.2024
name: Agnieszka Czmok
position: Product Manager

PRODUCT MANAGER
ZARYS International Group sp. z o.o. sp.k.
Agnieszka Czmok
.....
signature
(on behalf of the President of the General Partner's Management Board)