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:

ENEMA SET, non-sterile*

(*detailed list of products covered by this declaration is available in document TD-33-I.1.1.b-1.3– Identification – Annex 1, batch code - release document DZDO-01– Annex 2)

classification:

- class I, rule 5 (in accordance with Annex VIII of Regulation (EU) 2017/745)

Basic UDI-DI: 59079968G02060399EV

intended purpose: Disposable device that allows introduction of fluid into the large bowel through the anus to remove fecal material and stimulate peristaltic bowel movement.

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-33-I.4.c-1.3 - Annex 3.

place and date of issue: Zabrze, 1.12.2021
name: Bożena Smolnik
position: Product Manager

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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