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:

BETAtex
Medical gown, non-woven
models*: Medical gown, with elastic cuffs, non-woven, non-sterile
Medical gown with knitted cuffs, non-woven, non-sterile
Medical gown, isolation, with knitted cuffs, non-woven, laminated, non-sterile

(*detailed list of products covered by this declaration is available in document TD-30-I.1.1.b-2– 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: 59079968T0205R6

intended purpose: Disposable device intended for use by medical staff in hospital wards and emergency rooms during non-sterile medical procedures, as a barrier to limit the transfer of contaminants and/or potential infectious agents that may pose a risk to the patient due to his/her health condition.

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-2 - Annex 3.

place and date of issue: Zabrze, 1.12.2021
name: Aneta Kołazińska
position: Product Manager

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

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