

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
Shoe covers*

(*detailed list of products covered by this declaration is available in document TD-30-I.1.1.b-6 – 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: **59079968T0208RC**

intended purpose: Single-use medical device to be worn over footwear in the operating theatre area, intensive care units or in contact with immunocompromised patients, used as a barrier to minimise the transfer of contaminants that carry infectious agents into the surgical wound or onto the patient, 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-6 - 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.
A handwritten signature in blue ink, appearing to read "Agnieszka Czmok".
Agnieszka Czmok

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signature

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