

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

Medical mask

models*: **Medical mask, disposable, with earloops**

Medical mask, disposable, with ties

(*detailed list of products covered by this declaration is available in document TD-30-I.1.1.b-3 – 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: **59079968T020601HL**

intended purpose: A single-use medical device covering the mouth and nose, providing a barrier to minimise direct droplet transmission of infectious agents between medical staff and patients, used to protect the patient from infection and reduce the risk of spreading infection.

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-3 - 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

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signature

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