

EU DECLARATION OF CONFORMITY



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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 - release document 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: Disposable device covering the mouth and nose providing a barrier to minimize the direct transmission of infective agents between staff and patient.

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, 1.12.2021
name: Aneta Kołazińska
position: Product Manager

PRODUCT MANAGER
ZARYS International Group sp. z o.o. sp.k.

Aneta Kołazińska

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

