EU DECLARATION OF CONFORMITY

manufacturer: ZARYS International Group sp. z o.o. sp.k.
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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
Surgical cap with rubber
models*: Surgical cap with rubber POLA
Surgical cap with rubber MAYA
Surgical cap with snood DORA long

(*detailed list of products covered by this declaration is available in document TD-30-I.1.1.b-1.3 – 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: 59079968T0207RA

intended purpose: Single-use medical device intended for use by medical personnel during surgical interventions carried out in the operating theatre in order to prevent exfoliated epidermal particles and hair with infectious microorganisms present on them from reaching the operative wound from the operator's head, used for the prevention of surgical site infections.

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-1.3 - Annex 3.

Digitally signed by Granaci Boris
Date: 2025.06.25 11:12:29 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

place and date of issue: Zabrze, 13.11.2024
name: Agnieszka Czmok
position: Product Manager

PRODUCT MANAGER
ZARYS International Group sp. z o.o. sp.k.
Agnieszka Czmok
.....
signature
(on behalf of the President of the General Partner's Management Board)