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:

cellPAD

Cellulose swabs, perforated*

(*detailed list of products covered by this declaration is available in document TD-20-I.1.1.b-1 – Identification – Annex 1, batch code - release document DZDO-01– Annex 2)

classification:

class I, rule 4 (in accordance with Annex VIII of Regulation (EU) 2017/745)

Basic UDI-DI: 59079968M0299PU

intended purpose: Device is used for absorbing minor exudates, dressing minor cuts, abrasions on the skin and injection sites.

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-20-I.4.c-1 - Annex 3.

place and date of issue: Zabrze, 17.03.2023

name: Wioletta Wójcik
position: Product Manager

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

Wioletta Wójcik

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

