

# 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:

**orthoBAND**  
**Plaster of Paris bandage**

models\*: orthoBAND FAST, orthoBAND NORMAL, orthoBAND LONG

(\*detailed list of products covered by this declaration is available in document TD-04-I.1.1.b-1 – 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: 59079968M03050201HV

intended purpose: Disposable device intended for use as a full or partial dressing for stiffening/immobilisation in orthopaedic, ambulatory and surgical procedures.

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-04-I.4.c-1 - Annex 3.

place and date of issue: Zabrze, 1.12.2021  
name: Wioletta Gajda  
position: Product Manager

PRODUCT MANAGER  
ZARYS International Group sp. z o.o. sp.k.  
*Wioletta Gajda*  
Wioletta Gajda

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

