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EU DECLARATION OF CONFORMITY

The company PREVIS S.r.l. (SRN: IT-MF-000017072), with registered and operative headquarters in Viale dell'Industria, 32 TRISSINO (VI), as manufacturer of medical devices:

Denomination	Code	Basic UDI-DI Code
BANDAGE PREVIZINC A SINGLE CELL 5m x 10cm	ZINA050101	803314028ZINAXXXYY1N2
BANDAGE PREVIZINC A SINGLE CELL 6m x 8cm	ZINA060081	803314028ZINAXXXYY1N2
BANDAGE PREVIZINC E SINGLE CELL 5m x 10cm	ZINE050101	803314028ZINEXXXYY1Q6
BANDAGE PREVIZINC E SINGLE CELL 6m x 8cm	ZINE060081	803314028ZINEXXXYY1Q6
BANDAGE PREVIZINC E SINGLE CELL 7m x 10cm	ZINE070101	803314028ZINEXXXYY1Q6

bandages with zinc oxide paste, with intended use in trauma therapy as the action of compression promotes the reabsorption of hematomas, contusions, effusions due to sprains and tears and in the treatment of varicose veins, thrombophlebitis and phlebothrombosis; risk class IIa, in accordance with rule 21 of Annex VIII of EU Regulation 2017/745, declares under its total exclusive responsibility, that these medical devices

- comply with the general safety and performance requirements and the provisions of Regulation (EU) 2017/745 and subsequent amendments, as per the Technical Documentation stored at the company;
- no CS were used for the compliance of the aforementioned medical devices:
- they are manufactured in accordance with technical documentation n.: DT 006 PR, which meets the requirements set out in Annex II and III of the aforementioned Regulation:
- they are manufactured in accordance with the Quality System, which satisfies the requirements set out in Annex XI – Part A of the aforementioned Regulation, as per Certificate n. 0425-MDR-030043-00 issued on 02/10/2023, by ICIM S.p.a. – Notified Body n. 0425, - in Italy in Sesto San Giovanni (MI) in Piazza Don Enrico Mapelli, 75.

TRISSINO (VI), 31/10/2023

PREVIS S.r.l.
Direttore Generale
Michela Castagna