

EU Declaration of Conformity

Changxing Zhiwei Clothing Materials Co, LTD declares that this medical device complies with the following regulations:
It is produced in compliance with the essential health and safety requirements according to Regulation (EU) 2016/425 of the European Parliament and of Council of 09 March 2016 on personal protective equipment regulation and with the following reference standard: EN 149:2001 + A1:2009 Respiratory protective devices - Filtering half masks to protect against particles.

MANUFACTURER:	Changxing Zhiwei Clothing Materials Co, LTD No.8 Changqiao Road, Huaxi Zone, Changxing Country, Huzhou City, Zhejiang Province, China
PRODUCT:	FOLD FLAT MASK
PRODUCT NAME:	BALTIC MASKS
CLASSIFICATION:	FFP2 NR
MODEL:	BM-003V (fold flat mask with valve, single use only)
STANDARD:	EN149:2001+A1:2009,
CERTIFICATE:	Certificate Number: CW/PPER/1/12/2020 (Module B) CW/PPER/1/12/2020 (Module C2)
Regulation (EU) 2016/425 on personal protective equipment (PPE), Annex VII	
NOTIFIED BODY INFORMATION:	Polski Rejestr Statków S.A(NB ID: 1463) Hallera 126,80-416 Gdansk, Poland

This declaration applies to all specimens manufactured identical to the model submitted for evaluation. Assessment of compliance of the product with the requirements relating to safety standards and legal requirements listed above was performed by manufacturer.
Other relevant legal requirements for product and manufacturing have to be observed.



VILNIUS, LITHUANIA, DATE 2021 01 21
InSpe (BALTICMASKS Brand holder) CEO,
Guy Shapira



CHANGXING, CHINA, DATE 2021 01 21
Changxing Zhiwei Clothing Materials Co, LTD
General Manager Zou Yinzhi

长兴县志纬服装辅料有限公司
CHANGXING ZHIWEI CLOTHING MATERIALS CO.,LTD

This declaration is the responsibility of the Manufacturer