

EU Declaration of Conformity

CAREABLE Biotechnology Co. 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:	CAREABLE Biotechnology Co.,LT. Address:Building O, no. 3, Hongxing read, Jiangmen City, China
PRODUCT:	Particle Filtering Half Face with valve
PRODUCT NAME:	BALTIC MASKS
CLASSIFICATION:	FFP3 NR
MODEL:	BM-033V (cup shape, single use only)
STANDARD:	EN149:2001+A1:2009
CERTIFICATE:	Certificate Number: CW/PPER/2/12/2020 (Module B)
Regulation (EU) 2016/425 on personal protective equipment (PPE), Annex VII	Certificate Number: CW/PPER/3/12/2020 (Module C2)
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.



VILNUS, LITHUANIA, DATE 2020 12 06
InSpe (BALTICMASKS Brand holder) CEO,
Guy Shapira



CAREABLE Biotechnology Co.,LTD.
2020 12 06



Document valid until 2021 12 06

This declaration is the responsibility of the Manufacturer