

## DECLARATION OF CONFORMITY

DELTA PLUS GROUP declares that this product complies with the following regulations :

Identification of the medical device object of the declaration:

HM11001U\_

Designation :

BOX OF 50 TYPE II DISPOSABLE MEDICAL FACE MASKS.

Colour :

Blue-White

Size :

M/L



Specifications :

Dispenser box of 50 Type II disposable medical face masks. Class 1 medical device. 3 folds. Adjustable nose clip. Elastic ear loops. Non-woven polypropylene.

The medical device is also identifiable by the following means:

- The product picture
- Each medical device wears the name indicated on this declaration of conformity.
- Each medical device wears the bar code indicated in the annex to this declaration of conformity.
- Each medical device wears a batch number. Our organization, based on this batch number, allows us to ensure the traceability of the medical device.

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This declaration of conformity is issued under the sole responsibility of the manufacturer.

The object of the declaration identified above is in conformity with the relevant Union harmonization legislation:

93/42/EEC Directive, with its requirements, its annex VII and with the harmonized standards:

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## 93/42/EEC DIRECTIVE

### EN14683:2019 – Medical face masks - Requirements and test methods

Type II - Bacterial Filtration Efficiency  $\geq$  98%

### ISO 22609:2004 – Test method for resistance against penetration by synthetic blood

Resistance at 80mmHg

### EN ISO 13485:2016 – Medical devices - Quality management systems - Requirements for regulatory purposes

Apt, 22/04/2020

*Signed for and on behalf of*  
**DELTA PLUS GROUP :**  
David GUIHO – Marketing Director



## ANNEX:

References						
References	Bar code	COLOUR	SIZE	?	?	
HM11001U	3295249255770	Blue	M/L	40 boxes	50 Masks	
				52 x 39 x 38 cm	19 x 10 x 9 cm	