

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.

EU DECLARATION OF CONFORMITY

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:

EU REGULATION 2017/745, with its requirements and with the harmonized standards:

DECLARATION OF CONFORMITY



EU REGULATION 2017/745

EN14683:2019+AC: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, 26/05/201

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	