


EU DECLARATION OF CONFORMITY

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

| | | |
|------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|
| Registrant manufacturer | DELTA PLUS GROUP |  |
| Code – Product Name | HM11001U_ - HM11001U | |
| Product designation | Disposable mask - Non-Woven Synthetic - Foldable - Box of 50 | |
| Identification / Tracability | Each product wears a batch number. For any further information, simply give it to us. Our organization, on the basis of this batch number, allows us to ensure the traceability of the PPE. | |
| EUDAMED | FR-MF-000032965 | |
| IUD-ID | | |

This declaration of conformity is issued under the sole responsibility of the manufacturer. DELTA PLUS GROUP
 The product, subject of this declaration and identified above, complies with Regulation (EU) 2017/745 on Medical Devices and the following standards:



EN ISO13485:2016

EN14683:2019+AC:2019

ISO 22609:2004

Risk class I medical device

Apt, on 2024/10/09

**Signed by and name of DELTA PLUS GROUP:
 David GUIHO
 Marketing Director**



Appendices

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| Reference | EAN13 | Colour | Size |
|-----------|---------------|------------|-------|
| HM11001U | 3295249255770 | Blue-White | MD/LG |