# EC DECLARATION OF CONFORMITY[1]

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|---|---|
| **Manufacturer Name:** | ClearMask, LLC |
| **Manufacturer Address:** | 320 W 29th St Suite 200 Baltimore, MD 21211, USA |
| **Manufacturer SRN (Single Registration Number):** | [SRN is not yet issued] |
| **Authorized Representative Name (if applicable):** | MDSS GmbH |
| **Authorized Representative Address (if applicable):** | Schiffgraben 41, 30175 Hannover, Germany |
| **Authorized Representative SRN (if applicable):** | **DE-AR-000005430** |
| **Notified Body name (if applicable):** | N/A – no NB review |
| **Notified Body Address (if applicable):** | N/A – no NB review |
| **Notified Body Identification number (if applicable):** | N/A – no NB review |

We, ClearMask, LLC at 320 W 29th St Suite 200 Baltimore, MD 21211-2902 (the Manufacturer) hereby declare under the sole responsibility of the Manufacturer that the products listed in the Annex A. to this Declaration of Conformity meet the provisions of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices (the Regulation) and essential requirements which apply to them.

[1] This Declaration is drafted according to the minimum content requirements described on Annex IV of the Regulation (EU) 2017/745.

The above mentioned devices have been classified as Class I according to Rule#1 of Annex VIII of the Regulation and the fact that Rule #2 through Rule #4 do not apply. This declaration is based on the conformity assessment of the products to the requirements of Annex IV of the Regulation.

See in Annex A. of a list of device that is covered by this declaration of conformity. All devices fully conform with the applicable requirements in the Regulation.

All supporting documentation is retained at the premises of the manufacturer as well as the EU Authorized Representative.

| Signed on behalf of the Manufacturer | |
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| Print Name: Aaron Hsu<br>Function / Title: Chief Executive Officer<br><br>Signature:<br>DocuSigned by:<br>Aaron Hsu<br>8135C2A7239348C...<br>…… | Place and date of issuance:<br><br>Place: 320 W 29th St Suite 200 Baltimore, MD 21211, USA<br><br>Date: 7/28/2021 |

# Annex A. to the Declaration of Conformity

## Class I Medical Devices (according to Article 15 of the Regulation)

| No. | Code / Refernece No. | Product Name | Intended Use/Purpose per IFU | Basic UDI-DI | Classification | Classification Rule |
|---|---|---|---|---|---|---|
| 1. | CM002EZ | ClearMask™ Transparent Surgical Mask | The ClearMask Transparent Surgical Face Mask is intended for use in healthcare settings, such as in operating rooms, or in other medical procedures such as dental, isolation and veterinary procedures during which a face mask is necessary to protect both patient and healthcare personnel from transfer of body fluids, microorganisms, and particulate material. The device allows for full view of the face and facial expressions, particularly the nose and mouth areas.<br><br>The device is indicated for over-the-counter use. The device is disposable and is indicated for single use. The device is not provided sterile. | Pending UDAMED<br>Preliminary UDI-DI:<br>08600051060CSM-002JJ | Class 1 | Rule #1 |

# Revision History

| Revision No. | Description of Contents/Changes |
|---|---|
| 0 | Initial release - July 2021 |
| 1 | Updated to provide full device model number – July 2021 |