

Doc Number: QC/ECDC001

Declaration of Conformity

Manufacturer: Advanced Multi-Technology for Medical Industries-HITEX

Address: Building No. 27, Al Musa wah Str., Marj Al F aras Industrial Area, Shafa Badran,

P.O. Box 3707 Amman, 11953 Jordan.

We declare under our sole responsibility that the product(s) listed below to which declaration relates are in conformity with the applicable provisions of Directive 93/42/EEC as amended (2007/47/EC), concerning medical devices.

Product Name: Disposable Mask Ear Loop / Tie Mask.

Product Code: HN0050.

Color: White, Blue, Green, Gray.

This declaration is supported by:

- CE Certificate No. CE20322 (Valid from: 5th March 2020 until 4th March 2023).
- Manufactory License (GMP) Ref.No. 5/1/3/7927(Valid from: Feb 2020 until Feb 2023).
- Certificate of Registration of Quality Management System to EN ISO 13485:2016 Certificate No. MDS-20-03-21(Valid from: 5th March 2020 until 4th March 2023).
- Certificate of Registration of Quality Management System to EN ISO 9001:2015 Certificate No. MDS-20-03-21(Valid from: 5th March 2020 until 4th March 2023).

Managing Director

Signe:

Chava D

Date: 25-03-2020



Wasfi Al Tal St. - Amman Building No. 80 Fifth Floor Office No. 503 P.O.Box: 3707 Amman 11953 Jord