EU Declaration of Conformity

According to Medical Device Regulation (2017/745/EU)

Manufacturer

CMT Equipment Ltd T/A CMT Group Trident Works, Mulberry Way, Belvedere, Kent, DA17 6AN

Conformity Assessment Procedure

Annex IV of the Medical Device Regulation (MDR) 2017/745/EU

Product Identification

Brand: MAX

Model: Non-sterile IIR 3-ply medical face mask

Variant Code: SM120

Intended Use: single-use fluid resistant flat-pleated medical mask with ear loops intended to protect patients from large particles expelled by the wearer (e.g. saliva, mucus), or to prevent these particles from reaching the work environment

UDI: n/a

Medical Device Regulation

Class I (non sterile)

Other Harmonised Standards and/or Other Normative Documents/Technical Specifications

EN14683:2019

The medical device complies with the safety and performance requirements in accordance with Annex I of the Medical Device Regulation 2017/745/EU. We declare under our sole responsibility that the products to which this declaration relates are in conformity with the safety and performance requirements of Annex I of the above Regulation.

This DoC is valid until 06/05/2022.

Date: 06/05/2020

Title: Chloe Gray, Compliance Manager
On behalf of CMT Equipment Ltd T/A CMT Group