



# europcert

## CERTIFICATE OF COMPLIANCE

**CERTIFICATE No. 0239**

**MANUFACTURER**

**Calmedix Manufacturing PTE LTD**

**MANUFACTURER ADDRESS**

23 Tagore Lane. #04-08/09/10/11  
Tagore 23 Warehouse  
Singapore 787601

**DIRECTIVE(S)**

MDD 93/42/EEC - Class I, Rule 1

**NORMATIVE(S)**

EN 14683:2019+AC:201

**DEVICE NAME(S), EU-REG**

1. Disposable Face Mask  
Models: FORTIFY - F1 TYPE I, F2 TYPE IIR  
CM/MDF /01, 1 0-Feb-2021  
DE/CA20/05-Europcert-13/21

Based upon the review of the Technical File and Declaration of Conformity, the devices are deemed to meet the requirements of the above Medical Device Directive and hence fulfil the requirements of 93/42/EEC. It is the sole responsibility of the Manufacturer of the device(s) to perform all the necessary activities before placing the device(s) on the market. The Manufacturer is also responsible to maintain efficient internal production control to ensure the device(s) are in compliance with the regulatory requirements.



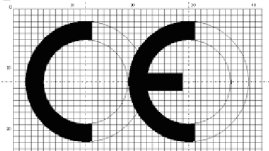
Joe Raj Kumar  
- General Manager -  
EuropeCert

**DATE OF ISSUANCE**  
February 27<sup>th</sup>, 2021

**CERTIFICATE VALIDITY**  
February 26<sup>th</sup>, 2022



DE/2021/CC/0239C



Corporate Office: EuropeCert Alstr. 97 - 41063 Mönchengladbach - Germany  
Tel. +49 (0) 2161 990 883 1 | Email: support@europcert.eu