



Document Number : INT-TF-Q0012

Version: A/1

EC DECLARATION OF CONFORMITY

Manufacturer

Name: INTCO Medical (HK) Co., Ltd.
Address: Flat/RM 19c, Lockhart Centre
301-307 Lockhart road, Wan Chai, Hong
Kong

Authorized Representative

Name: Lotus NL B.V.
Address: Koningin Julianaplein 10, 1e Verd,
2595AA, The Hague, Netherlands.

Declares that the MDD described hereafter

Product name and model:

Disposable Medical Face Masks

FM101; FM201; FM301

UMDNS code: 12458

Meet the provisions of the Council Directive 93/42/EEC and mended by DIRECTIVE 2007/47/EC of 5 September 2007" which apply to the Masks.

Verification to: Standard EN 14683-2019

The medical device has been assigned to class I according to Annex IX of the Directive 93/42/EEC. It bears the mark



CONFORMITY ASSESSMENT ROUTE: ANNEX IX Rule 1

This Declaration of conformity is valid in connection with the release document for the respective batch of produced devices.

The above mentioned declaration of conformity is exclusively under the responsibility of

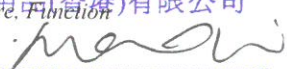
Company: INTCO Medical (HK) Co., Ltd.

Address: Flat/RM 19c, Lockhart Centre 301-307 Lockhart road, Wan Chai, Hong Kong

Shanghai 2017-08-20

Place, date

EC Declaration of Conformity

For and on behalf of
INTCO MEDICAL (HK) CO., LIMITED
英科醫療用品(香港)有限公司
Legally binding signature

Authorized Signature(s)