

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 Masks FM301 UMDNS code: 12458

Meet the provisions of the Council Directive 93/42/EEC 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

CE

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 2019-05-20

Place, date

For and on behalf of INTCO MEDICAL HK) CO., LIMITED

Legally binding signature, themietich ignature(s)