CE

EC DECLARATION OF CONFORMITY

According to Council Directive 93/42/EEC concerning medical devices,

Manufacturer: Multibrands International Ltd.

Address: Royds Hall, Royds Hall Lane, Bradford BD12 0EJ.

European Representative: Lotus NL B.V.

Contact person: Peter E-mail: peter@lotusnl.com

Address: Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.

Product Name:

Panodyne Disposable Medical Mask (non-sterile)

Models: FB2RM-U(Type IIR), FB1RM-U(Type I)

Product classification: Class I

Applicable Standards:

EN ISO 14971:2019
EN ISO14683:2019
EN ISO10993-10:2010
MEE DEV 2.7.1 rev.4.0
EN ISO 15223-1:2016
EN ISO 10993-1:2018
EN ISO 13485:2016
EN 1041:2008
EN ISO10993-5:2009
93/42/EEC

We, the manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 93/42/EEC which apply to them.
The medical device has been assigned to class I according to Annex of the Directive 93/42/EEC.
We agree to develop, implement and maintain a documented post-production monitoring process.

Signed on 12/06/2020

Place: United Kingdom

Name of authorized signatory:

Position held in the company: General Manager

Seal/Stamp:

Multibrands International Ltd.

MULTIBRANDS INTERNATIONAL LIMITED
MULTIBRANDS™
REGISTERED IN ENGLAND 3680871