

DECLARATION OF CONFORMITY

We, Clement Clarke International Limited,
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Declare under our sole responsibility that the product listed below to which this declaration relates, is in conformity with the requirements of the Medical Devices Directive 93/42/EEC, Annex V (Metrology Aspects only).

Refer to Product Schedule GI/CCI/2016704 for a complete list of part codes and descriptions.

DESCRIPTION: Expiratory Peak Flow Meter Range

CLASSIFICATION: The device has been classified as class 1, with a measuring function, in accordance with Annex IX, rule 5 and complies with Annex 1, essential requirements of the Council Directive 93/42/EEC on Medical Devices.

The Notified Body responsible for carrying out those elements of the Directive requiring NB intervention is SGS United Kingdom Ltd, 202b Worle Parkway, Weston-Super-Mare, United Kingdom. CE0120.

MDD CLASSIFICATION: Class 1 (with a measuring function)

Rule 5: applicable, invasive device with respect to a body orifice, transient use, non-active medical device.

GMDN CODE: 46872- Peak Flow Meter, Manual

Applicable Harmonised Standards: Refer to HS/CCI/2015426

Authorised By:

Signed: 
Mr G Ostacchini
Group Quality & Regulatory Affairs Manager

Date: 22nd Nov 2018.