V 2 Page 1 of 1

Title; Declaration of Conformity- Adult and Paed Universal Mouthpiece and adaptor

DECLARATION OF CONFORMITY

We. Clement Clarke International Limited,

of. Edinburgh Way, Harlow. Essex, CM20 2TT. U.K.

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 II. 1

Universal Adult and Paediatric Mouthpieces **DESCRIPTION:**

and adaptor for use with Peak Flow Meters.

PART NUMBER(S): 3103051, 3103095, 3104033, 3105019

CLASSIFICATION: The device (s) has been classified as class I medical

> device under rule 5 as per Annex IX, and complies with Annex 1, essential requirements of the Council Directive

MDD 93/42/EEC.

GMDN CODE: 43467 Breathing Mouthpiece, reusable

Authorised By:

4 Allen

Date: 19th Aug 2015.

Mr G Ostacchini Group Quality and Regulatory Affairs Manager Clement Clarke International Ltd. Edinburgh Way, Harlow, Essex, CM20 2TT. U.K.