



EU Declaration of Conformity

For Pinnacle Peak Flow Meter

European Communities Council Directives 93/42/EEC as amended by 2007/47/EC concerning Medical Devices as transposed into European national law by member states

The undersigned declares that the products described in this document meet the Council Directive provisions that apply to them and the CE Mark may be affixed.

General Product Name:	Pinnacle Peak Flow Meter
Legal Manufacturer:	Fyne Dynamics Ltd., 1 Horsecroft Place, Harlow CM19 5BT, UK
Variants:	Identical product branded for various customers.
Intended Use:	For monitoring peak expiratory flowrate in respiratory conditions such as asthma.
MDD Classification:	Class 1m
Notified Body:	SGS Belgium NV, Notified Body 1639
CE Certificate Ref.	GB19/964476
EU Authorised Representative:	Advena Limited, Tower Business Centre, 2 nd Flr., Tower Street, Swatar, BKR 4013 Malta
MDD Conformity Assessment Route:	Product Quality Assurance outlined in Annex V.

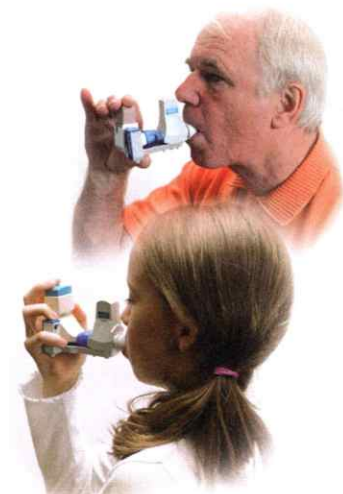
Name: John McNaughton

Position: Managing Director

Signed: 

Date: 05/01/2021

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the product is placed on the market under this manufacturer's name regardless of whether these operations are carried out by the manufacturer or on his behalf by a third party.



Fyne Dynamics Ltd.

05/01/2021

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Appendix I – Applicable Standards

This present declaration is also in conformity with the following European Standards and Common Specification:

Standard/Document Name	Description
93/42/EEC	Council Directive concerning medical devices as amended by Directive 2007/47/EC
EN 1041:2008	Information supplied by the manufacturer of medical devices
EN ISO 13485:2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971:2012	Medical Devices – Application of Risk Management to Medical Devices
EN ISO 15223-1:2016	Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied
EN ISO 23747:2015	Anaesthetic and respiratory equipment – Peak expiratory flow meters for the assessment of pulmonary function in spontaneously breathing humans.

Appendix II – Product Listing/Schedule

Part/Catalogue Number	Description/Name	GMDN Code
72000	Pinnacle Peak Flow Meter	46872

Version History

Version	Compiled By	Date	Description
1.0	J McNaughton	05/01/2021	First Issue