

EC DECLARATION OF CONFORMITY

Manufacturer: **Smart Respiratory Products Ltd.**

Registered Office: **33 Riding House Street, W1W 7DZ London, United Kingdom**

Product Description: **Peak expiratory flow meter with software application**

Product Name: **Smart Peak Flow**

is in conformity with provisions of the applied 93/42/EEC directive concerning medical devices (amended by 2007/47/EC of the European Parliament), as a **class II. a medical device.**

EC Certificate Registration Number: **144797-18-11-08**

Issued: **08 November 2018**

Expires: **07 November 2021**

Harmonised standards applied:

EN 60601-1:2015;

EN 60601-1-2:2015;

EN 60601-1-6:2010;

IEC 62366-1:2015;

EN ISO 10993-1:2018;

EN ISO 23747:2015;

EN 62304:2006;

EN ISO 13485:2016;

EN ISO 14971:2013

Name of Notified Body: **CE CERTISO Kft**

Address of Notified Body: Gyár u. 2, 2040 Budaörs, Hungary

Notified Body Number: **NB2409**

Quality Management System Certificate Registration Number: **14796-18-11-08**

Issued: **08 November 2018**

Expires: **07 November 2021**



Thomas Antalffy
Managing Director