

## EC DECLARATION OF CONFORMITY

Manufacturer: **Smart Respiratory Products Ltd.**

Registered Office: **Imperial I-Hub Level 4, 84 Wood Lane, White City London, England, W12 0BZ**

EU Authorized Representative: **Smart Respiratory Manufacturing Kft.**

Registered Office (EC rep): **HU, 1113 Budapest, Ibrahim utca 14.**

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, Annex II excluding (4) (amended by 2007/47/EC of the European Parliament), as a **class II.a medical device**.

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

Issued: **13 January 2021**

Expires: **07 November 2023**

Harmonised standards applied:

EN 60601-1;

EN 60601-1-2;

EN 60601-1-6;

IEC 62366-1;

EN ISO 10993-1;

EN ISO 23747;

EN 62304;

EN ISO 13485;

EN ISO 14971

Name of Notified Body: **CE Certiso Orvos- és Kórháztechnikai Ellenőrző és Tanúsító Korlátolt Felelősségű Társaság**

Address of Notified Body: Erdő utca 101, 2092 Budakeszi, Hungary

Notified Body Number: **NB2409**

Quality Management System Certificate Registration Number: **145184-22-01-07**

Issued: **07 January 2022**

Expires: **06 January 2025**

Issued: 21 January 2022



Thomas Antalffy  
**Managing Director**