Penlon

# Declaration of Conformity

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|---|---|
| **Manufacturer** | Penlon Limited, Abingdon Science Park,<br>Barton Lane, Abingdon, OX14 3NB, UK |
| **Product Name** | Penlon Oxygen Therapy Flowmeters & Bubble Humidifiers |
| **Classification** | Class IIa, Rule 2 |
| **Conformity Assessment Route** | Annex II |
| **GMDN Code** | Flowmeters (61365), Bubble Humidifiers (35113) |
| **Quality Management System** | ISO 13485:2016 |
| **Notified Body** | SGS Belgium NV, Noorderlaan 87, BE-2030 Antwerpen, Belgium<br>(**ID Number:** 1639) |
| **CE Certificate Number** | GB20/965349 |
| **Start of CE Marking** | 1999 |
| **European Authorised Representative** | Obelis s.a.<br>Bd. Général Wahis 53, 1030-Brussels, Belgium |

We hereby declare that the above mentioned products meet the provisions of the Council Directive 93/42/EEC for Medical Devices, as amended by Directive 2007/47/EC.
All supporting documentation is retained at the premises of the manufacturer.

**Place and Date of Issue** Abingdon, 24th May 2023

**Signed by:**

Mary P Ryan

SIGNATURE

**Mary Ryan**

PRINT NAME

**Director of Innovation, Technology & Regulatory Affairs EU PRRC**

POSITION