

## Declaration of Conformity

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<b>Manufacturer</b>	Penlon Limited, Abingdon Science Park, Barton Lane, Abingdon, OX14 3NB, UK
<b>Product Name</b>	Sigma EVA Vaporizer
<b>Classification</b>	Class IIb, Rule 11
<b>Conformity Assessment Route</b>	Annex II
<b>GMDN Code</b>	36979
<b>Quality Management System</b>	EN ISO 13485:2016
<b>Notified Body</b>	SGS Belgium NV, Noorderlaan 87, BE-2030 Antwerpen, Belgium (ID Number: 1639)
<b>CE Certificate Number</b>	GB20/965349
<b>Start of CE Marking</b>	10th March 2017

Penlon hereby declare that the Sigma EVA anaesthetic vaporiser meets the provisions of European Council Directive 93/42/EEC for Medical Devices, as amended by European Directive 2007/47/EC.

All supporting documentation is retained at the premises of the manufacturer.

**Place and Date of Issue:** Abingdon, 5<sup>th</sup> March 2020

**Signed on behalf of Penlon by:**



SIGNATURE

**Mary P Ryan**

PRINT NAME

**Director of Quality Assurance and Regulatory Affairs**

POSITION