

## 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 (Desflurane)
<b>Quality Management System</b>	ISO 13485:2016
<b>Notified Body</b>	SGS Belgium NV, Noorderlaan 87, BE-2030 Antwerpen, Belgium ( <b>ID Number:</b> 1639)
<b>CE Certificate Number</b>	GB20/965349
<b>Start of CE Marking</b>	10th March 2017
<b>European Authorised Representative</b>	Obelis s.a. 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, 26th July 2023

**Signed by:**



SIGNATURE

**Daniel Harrison**

PRINT NAME

**QARA Manager  
EU PRRC**

POSITION



## Appendix

#	Medical Device Name	Model/Version (Product)	Catalogue/ Reference (part number or configuration)	Basic UDI	MHRA Registration no.
1	Desflurane anaesthesia vaporiser	Sigma EVA Vaporizer Desflurane Generic	Not applicable	05051977000420	2022041401258106
		Sigma EVA Vaporizer Desflurane with Baxter Safe-Fill system	DDBS PNENS	05051977000420	2022042702260156
		Sigma EVA Vaporizer Desflurane with Piramal Fill system	DDPA PLENB	05051977000420	2022042702260161
		Sigma EVA Vaporizer Desflurane with Baxter Safe-Fill system, Drager Auto-exclusion and Plug-in (dual compatibility)	DDBA PNENH (0206042-1)	05051977000420	2023072602314730
		Sigma EVA Vaporizer Desflurane with Baxter Safe-Fill system, Selectatec compatible	DDBS PNENH (0206042)	05051977000420	2023072602314730

Signed By:

Daniel Harrison  
QARA Manager  
EU PRRC