

Declaration of Conformity

Manufacturer	Penlon Limited, Abingdon Science Park, Barton Lane, Abingdon, OX14 3NB, UK
Product Name	Sigma Delta Vaporizer Sigma Delta MRI Vaporizer
Classification	Class IIb, Rule 11
Conformity Assessment Route	Annex II
GMDN Code	36980 (Sevoflurane); 36890 (Isoflurane); 36891 (Halothane)
Quality Management System	ISO 13485:2016
Notified Body	SGS Belgium NV, Noorderlaan 87, BE-2030 Antwerpen, Belgium (ID Number: 1639)
CE Certificate Number	GB20/965349
Start of CE Marking	9 th February 2000

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 and the Canadian requirements as stated in the CMDR.
All supporting documentation is retained at the premises of the manufacturer.

Place and Date of Issue Abingdon, 5th March 2020

Signed by:



SIGNATURE

Mary Ryan

PRINT NAME

Director of Quality Assurance and Regulatory Affairs

POSITION