

Declaration of Conformity

Manufacturer	Penlon Limited, Abingdon Science Park, Barton Lane, Abingdon, OX14 3NB, UK
Product Name	Prima 400 Series Anaesthesia Machine
Models	Prima 440 Prima 445 Prima 450 Prima 460 Prima 465 Prima 451 MRI
Classification	Class IIb, Rule 11
Conformity Assessment Route	Annex II
GMDN Code	37710
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	2013
European Authorised Representative	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, 29th July 2021

Signed by:



SIGNATURE

Mary Ryan

PRINT NAME

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

POSITION