

Declaration of Conformity

Manufacturer	Penlon Limited, Abingdon Science Park, Barton Lane, Abingdon, OX14 3NB, UK
Product Name	AV-S Ventilator AV-S MRI Ventilator
MRI Rating	1.5 & 3.0 Tesla Magnet
Classification	Class IIb, Rule 11
Conformity Assessment Route	Annex II
GMDN Code	34851
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	10 th March 2017
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, 19th September 2023

Signed by:



SIGNATURE

Daniel Harrison

PRINT NAME

QARA Manager, EU PRC

POSITION

Appendix A: Product Identification

Product Type	Cat No.	Product Description	Basic UDI-DI	GMDN
Anaesthesia ventilator	5006414	AV-S Ventilator	5051977VENT-AVSAS	34851
	5008394	AV-S MRI Ventilator	5051977VENT-AVSMRIYN	

Accessories:

Cat No.	Product Description
5007503	Paediatric Bellows Kit, includes adaptor, canister and bellows assembly
102714	Oxygen sensor (located in the A200SP absorber) Used with AV-S ventilator only

Signed By:



Daniel Harrison
QARA Manager, EU PRRC