

Declaration of Conformity

Manufacturer	Penlon Limited, Abingdon Science Park, Barton Lane, Abingdon, OX14 3NB, UK
Product Name	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

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, 5th March 2020

Signed by:



SIGNATURE

Mary Patricia Ryan

PRINT NAME

Director Quality Assurance & Regulatory Affairs

POSITION