PHILIPS

Philips Medical Systems Nederland B.V.

Veenpluis 6, 5684 PC Best, The Netherlands

Compatibility Statement

Penlon Limited, Abingdon Science Park, Barton Lane, Abingdon, OX14 3NB, UK markets the devices listed below (hereinafter referred to as “Product”).

Philips Medical Systems Nederland B.V. has performed compatibility tests utilizing a limited number of samples of Product on 22nd March 2022. The scope of this compatibility statement is strictly limited to the below listed Philips MRI systems (hereinafter “MRI System”) and Product.

Philips Part			**Penlon Product**	
Philips MRI system	**6NC MDD**	**6NC MDR**	**Part**	**Description**
Achieva 1.5T	781343	n.a.	Prima 451 “MI5” MRI	Anaesthesia machine
Achieva 1.5T dStream	781262	n.a.	AV-S MRI “AVSPM” MRI	Ventilator
Ingenia 1.5T CX	781262	782104	Delta “MR”	Iso, Sevo and Hal vaporizers
Smartpath to dStream 1.5T	781260	782112	SC760 MRI	Suction controller
Ingenia 1.5T	781341	782101	AGSS MRI	Scavenging receiver
Ingenia 1.5T S	781347	782102		
Ingenia Ambition 1.5T S	781359	782108		
Ingenia Ambition 1.5T X	781356	782109		
Ingenia 1.5T (Evolution)	781315	782115		
MR5300 1.5T	781315	782110		
Evolution upgrade 1.5T (transf)	n.a.	782116		
Achieva 3.0T	781278	n.a.		
Achieva 3.0T Tx	781345	n.a.		
Achieva 3T dStream	781271	n.a.,		
Ingenia 3.0T CX	781271	782105		
Smartpath to dStream for XR and 3T	781270	782113		
Ingenia Omega HP 3.0T	781342	782103		
Ingenia 3.0T	781342	n.a.		
Ingenia Elition 3.0T S	781357	782106		
Ingenia Elition 3.0T X	781358	782107		
MR7700 3.0T	n.a.	782120		
Evolution upgrade 3T (transf)	n.a.	782117		

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Philips Part			Penlon Product	
Philips MRI system	**6NC MDD**	**6NC MDR**		
Smartpath to Ingenia Elition X	n.a.	782118		
Prodiva 1.5T CS	781069	n.a.		
Prodiva 1.5T CX	781070	n.a.		
Multiva 1.5T	781072 781073	n.a.		

Through the basic compatibility testing with the Product, Philips found the MRI System performed as intended and specified, with no detrimental degradation of MRI System efficacy or safety when used per the conditions as stated in their Instructions for Use. This testing indicates compatibility of the Product with MRI System.

Safety and efficacy of the Product is the sole responsibility of Penlon Limited. All issues related to the use of Product shall be referred to Penlon Limited. This compatibility statement does not guarantee assurance that compatibility will be maintained with future changes to Product, including incorporated software releases, modifications, and upgrades.

Compatibility testing reference file: D001057330 Rev.A

Philips Medical Systems Nederland B.V

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(signature)

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