

EU DECLARATION OF CONFORMITY

Manufacturer

Penlon Limited,
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Abingdon, OX14 3NB, UK

EC Authorized Representative

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Single Registration Number (SRN): GB-MF-000025115

SRN: BE-AR-000000106

This declaration is issued under our sole responsibility of the legal manufacturer.

Product Type	: Vacuum Suction Controller
Product Identification	: SC760 High Suction Controller SC760 Low Suction Controller SC760 Intermittent Suction Controller SC760 Twin Suction Controller SC760 MRI High Suction Controller
Basic-UDI-DI	: Refer Appendix A
Risk Classification & Rule	: Class I, Rule 2
Conformity Assessment Procedure	: Annex II
Intended Use	: Suction Controllers and accessories are intended for general hospital aspiration procedures.

We hereby declare, the conformity of the above mentioned products with Regulation (EU) 2017/745 of the European Parliament and of the Council and, if applicable, with any other relevant Union legislation that provides for the issuing of an EU declaration of conformity.

The products compliance with general safety and performance requirements **Annex I** of Regulation (EU) **2017/745** and applicable standards are listed in the respective Technical Documentation.

Place and Date of issue: Abingdon, 30 June 2023

Signed by:



Daniel Harrison
QARA Manager, PRRC



This declaration will be renewed on any significant change of product, product range, standards and laws.

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Appendix A: Product Identifications

Product Name	Cat No.	Product Description	Basic UDI-DI	GMDN
SC760 High Suction controller	310101	SC760 Suction Controller- High, Direct probe	5051977SCO-SC7608H	44809
	310101-DIN	SC760 Suction Controller- High, Direct probe, DIN		
	310103	SC760 Suction Controller- High, Remote, with 'V' plate		
	310105	SC760 Suction Controller- High, Remote with 44 mm rail clamp		
	310107	SC760 Suction Controller- High with 1/8" NPT Universal thread		
	310118	SC760 Suction Controller- High, AFNOR		
	315003/SC760	SC760 Suction Controller- Mobile Suction Trolley, High, with 3 V sockets, tubing & taper		
	5008959	SC760 Suction Controller Kit for Prima Workstations- High, Remote, with 'V' plate, vacuum hose & BS probe		
	9910-244/SC760	SC760 Suction Controller- Theatre Suction Kit, High, with remote Mk4 probe, 2 V sockets, tubing & taper		
	9910-147/SC760	SC760 Suction Controller- Theatre Suction Kit, High, with remote Mk4 probe, 2 parallel sockets		
SC760 Low Suction controller	310102	SC760 Suction Controller- Low, Direct probe	5051977SCO-SC7608H	44809
	310102-DIN	SC760 Suction Controller- Low, Direct probe, DIN		
	310104	SC760 Suction Controller- Low, Remote, with 'V' plate		
	310106	SC760 Suction Controller- Low, Remote, with 44 mm rail clamp		
	500328	SC760 Suction Controller- Low, AFNOR		
SC760 Intermittent Suction controller	310165	Intermittent suction controller- High with 1/8" NPT Universal thread	5051977SCO-SC7608H	44809
SC760 Twin Suction Controller	310109	Twin SC760 Suction Controller- High, Direct probe	5051977SCO-SC7608H	44809
SC760 MRI High Suction controller	5006846	SC760 MRI Suction kit. High suction, with forward facing mounting system and 2m hose	5051977SCO-SC760MRIU9	44809
	5007495	SC760 MRI Suction kit. High suction, with forward facing mounting system and 4m hose		
	5009921	SC760 MRI Suction kit. High suction, AFNOR with direct Air Liquide probe and 1m hose		
	5009919	SC760 MRI Suction kit. High suction, DIN with direct probe and 1m hose		

Accessories

Product Name	Cat No.	Product Description	GMDN
Suction system filter, microbial	4830-014	Penlon BactiTrap, single	37798
	9970-001	Penlon BactiTrap, box of 48	