

Declaration of Conformity

Manufacturer	Penlon Limited, Abingdon Science Park, Barton Lane, Abingdon, OX14 3NB, UK
Product Name	Sigma Delta Vaporizer Sigma Delta MRI Vaporizer
Classification	Class IIb, Rule 11
Conformity Assessment Route	Annex II
GMDN Code	36980 (Sevoflurane); 36890 (Isoflurane); 36891 (Halothane)
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	9 th February 2000
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, 26th July 2023

Signed by:



SIGNATURE

Daniel Harrison

PRINT NAME

**QARA Manager
EU PRRC**

POSITION

Appendix

#	Medical Device Name (GMDN code)	Model/Version (Product)	Catalogue/ Reference (part number or configuration)	Basic UDI	MHRA Registration no.
1	Halothane anaesthesia vaporizer (36891)	Sigma Delta MRI Vaporizer Halothane Generic	Not applicable	05051977000116	2022041401258108
		Sigma Delta MRI Vaporizer Halothane 5%, key fill	VH5KS MRXZ	05051977000116	2023022302296644
		Sigma Delta MRI Vaporizer Halothane 5%, key fill, with bottle adaptor	VH5KS MRXK	05051977000116	2023022302296644
		Sigma Delta Vaporizer Halothane Generic	Not applicable	05051977000116	2022041401258113
		Sigma Delta Vaporizer Halothane 5% Selectatec, pour filler	VH5PS XXXZ	05051977000116	2023022302296644
		Sigma Delta Vaporizer Halothane 5% Selectatec, key filler	VH5KS XXXZ	05051977000116	2023022302296644
		Sigma Delta Vaporizer Halothane 5% Selectatec, key filler with adaptor	VH5KS XXXK	05051977000116	2023022302296644
		Sigma Delta Vaporizer Halothane 5% Cagemount, pour filler	VH5PC XXXZ	05051977000116	2023022302296644
		Sigma Delta Vaporizer Halothane 5% Cagemount, key filler	VH5KC XXXZ	05051977000116	2023022302296644
		Sigma Delta Vaporizer Halothane 5% Cagemount, key filler with adaptor	VH5KC XXXK	05051977000116	2023022302296644
		Sigma Delta Vaporizer Halothane 5% Dräger Plug-In, pour filler	VH5PD XXXZ	05051977000116	2023022302296644
Sigma Delta Vaporizer Halothane 5% Dräger Auto-exclusion, pour filler	VH5PA XXXZ	05051977000116	2023022302296644		
2	Isoflurane anaesthesia vaporizer (36890)	Sigma Delta Vaporizer Isoflurane Generic	Not applicable	05051977000116	2022041401258115
		Sigma Delta Vaporizer Isoflurane 5% Selectatec, key filler with adaptor	VI5KS XXXK	05051977000116	2023022302296645
		Sigma Delta MRI Vaporizer Isoflurane	VI5KS MRXZ	05051977000116	2023022302296645
		Sigma Delta Vaporizer Isoflurane 5% Selectatec, pour filler	VI5PS XXXZ	05051977000116	2023022302296645
		Sigma Delta Vaporizer Isoflurane 5% Selectatec, key filler	VI5KS XXXZ	05051977000116	2023022302296645
		Vaporizer Penlon, Isoflurane Delta Key-fill, Selectatec incl. Key-fill adapter für Isof. Flaschen	VI5KS HLEK (0206041)	05051977000116	2023072602314719
		Sigma Delta Vaporizer Isoflurane 5% Cagemount, pour filler	VI5PC XXXZ	05051977000116	2023022302296645
		Sigma Delta Vaporizer Isoflurane 5% Cagemount, key filler	VI5KC XXXZ	05051977000116	2023022302296645
		Sigma Delta Vaporizer Isoflurane 5% Cagemount, key filler with adaptor	VI5KC XXXK	05051977000116	2023022302296645
		Sigma Delta Vaporizer Isoflurane 5% Dräger Plug-In, pour filler	VI5PD XXXZ	05051977000116	2023022302296645
		Sigma Delta Vaporizer Isoflurane 5% Dräger Plug-In, key filler	VI5KD XXXZ	05051977000116	2023022302296645
		Narkosemittel-Verdampfer Penlon, Isoflurane Delta Key-fill, mit Dräger Adapter incl. Key-fill Adapter für Isof. Flaschen	VI5KD HLEK (0206041-1)	05051977000116	2023072602314719
		Sigma Delta Vaporizer Isoflurane 5% Dräger Plug-In, key filler with adaptor	VI5KD XXXK	05051977000116	2023022302296645
		Sigma Delta Vaporizer Isoflurane 5% North American Dräger, pour filler	VI5PN XXXZ	05051977000116	2023022302296645
		Sigma Delta Vaporizer Isoflurane 5% North American Dräger, key filler	VI5KN XXXZ	05051977000116	2023022302296645
		Sigma Delta Vaporizer Isoflurane 5% North American Dräger, key filler with adaptor	VI5KN XXXK	05051977000116	2023022302296645
		Sigma Delta Vaporizer Isoflurane 5% Dräger Auto- exclusion, pour filler	VI5PA XXXZ	05051977000116	2023022302296645
		Sigma Delta Vaporizer Isoflurane 5% Dräger Auto- exclusion, key filler	VI5KA XXXZ	05051977000116	2023022302296645
		Sigma Delta Vaporizer Isoflurane 5% Dräger Auto- exclusion, key filler with adaptor	VI5KA XXXK	05051977000116	2023022302296645
		Sigma Delta MRI Vaporizer Sevoflurane Generic	Not applicable	05051977000116	2022042001258834
		Sigma Delta MRI Sevoflurane 8%, key filler	VS8KS MRXZ	05051977000116	2023022402296907

3	Sevoflurane anaesthesia Vaporizer (36980)	Sigma Delta MRI Sevoflurane 8%, key filler with adaptor	VS8KS MRXK	05051977000116	2023022402296907		
		Sigma Delta MRI Sevoflurane 8%, Quik-Fil	VS8QS MRXZ	05051977000116	2023022402296907		
		Sigma Delta Vaporizer Sevoflurane Generic	Not applicable	05051977000116	2022042001258840		
		Sigma Delta Sevoflurane 8%, Selectatec, pour filler	VS8PS XXXZ	05051977000116	2023022402296907		
		Sigma Delta Sevoflurane 8%, Selectatec with Interlock, key filler	VS8KS XXXZ	05051977000116	2023022402296907		
		Sigma Delta Sevoflurane 8%, Selectatec with Interlock, key filler with adaptor	VS8KS XXXK	05051977000116	2023022402296907		
		Sigma Delta Sevoflurane 8%, Selectatec, Quik-Fil	VS8QS XXXZ	05051977000116	2023022402296907		
		Sigma Delta Sevoflurane 8%, Selectatec, Quik-Fil with drain funnel and key assembly	VS8QS XXXQ	05051977000116	2023022402296907		
		Vaporizer Penlon Sevoflurane; Delta Quik-fill, Selectatec incl. Quik-fill adapter für Sev. Flaschen	VS8QS HLEQ (0206040)	05051977000116	2023072602314723		
		Sigma Delta Vaporizer Sevoflurane 8% Cagemount, with pour filler	VS8PC XXXZ	05051977000116	2023022402296907		
		Sigma Delta Vaporizer Sevoflurane 8% Cagemount, with key filler	VS8KC XXXZ	05051977000116	2023022402296907		
		Sigma Delta Vaporizer Sevoflurane 8% Cagemount, with key filler and adaptor	VS8KC XXXK	05051977000116	2023022402296907		
		Sigma Delta Vaporizer Sevoflurane 8% Cagemount, with Quik-Fil	VS8QC XXXZ	05051977000116	2023022402296907		
		Sigma Delta Vaporizer Sevoflurane 8% Cagemount, with Quik-Fil, drain funnel & key assembly	VS8QC XXXQ	05051977000116	2023022402296907		
		Sigma Delta Vaporizer Sevoflurane 8% Dräger Plug-In, pour filler	VS8PD XXXZ	05051977000116	2023022402296907		
		3	Sevoflurane anaesthesia vaporizer (cont.) (36980)	Sigma Delta Vaporizer Sevoflurane 8% Dräger Plug-In, key filler	VS8KD XXXZ	05051977000116	2023022402296907
				Sigma Delta Vaporizer Sevoflurane 8% Dräger Plug-In, key filler with adaptor	VS8KD XXXK	05051977000116	2023022402296907
Sigma Delta Vaporizer Sevoflurane 8% Dräger Plug-In, Quik-Fil	VS8QD XXXZ			05051977000116	2023022402296907		
Sigma Delta Vaporizer Sevoflurane 8% Dräger Plug-In, Quik-Fil with drain funnel and key	VS8QD XXXQ			05051977000116	2023022402296907		
Narkosemittel-Verdampfer Penlon Sevoflurane; Delta Quik-fill, mit Dräger Adapter incl. Quik-fill Adapter für Sev. Flaschen	VS8QD HLEQ (0206040-1)			05051977000116	2023072602314723		
Sigma Delta Vaporizer Sevoflurane 8% North American Dräger, pour filler	VS8PN XXXZ			05051977000116	2023022402296907		
Sigma Delta Vaporizer Sevoflurane 8% North American Dräger, key filler	VS8KN XXXZ			05051977000116	2023022402296907		
Sigma Delta Vaporizer Sevoflurane 8% North American Dräger, key filler with adaptor	VS8KN XXXK			05051977000116	2023022402296907		
Sigma Delta Vaporizer Sevoflurane 8% North American Dräger, Quik-Fil	VS8QN XXXZ			05051977000116	2023022402296907		
Sigma Delta Vaporizer Sevoflurane 8% North American Dräger, Quik-Fil with drain funnel and key	VS8QN XXXQ			05051977000116	2023022402296907		
Sigma Delta Vaporizer Sevoflurane 8% Dräger Auto- exclusion, pour filler	VS8PA XXXZ			05051977000116	2023022402296907		
Sigma Delta Vaporizer Sevoflurane 8% Dräger Auto- exclusion, key filler	VS8KA XXXZ			05051977000116	2023022402296907		
Sigma Delta Vaporizer Sevoflurane 8% Dräger Auto- exclusion, key filler with adaptor	VS8KA XXXK			05051977000116	2023022402296907		
Sigma Delta Vaporizer Sevoflurane 8% Dräger Auto- exclusion, Quik-Fil	VS8QA XXXZ			05051977000116	2023022402296907		
Sigma Delta Vaporizer Sevoflurane 8% Dräger Auto- exclusion, Quik-Fil with drain funnel and key	VS8QA XXXQ			05051977000116	2023022402296907		

Catalogue Reference number Key: X = variable field. Refer to “Clarification Statement for Sigma Delta Vaporizer Models”.



Signed By:

A handwritten signature in grey ink, appearing to read "Daniel Harrison".

Daniel Harrison
QARA Manager
EU PRRC