Penlon

UK DECLARATION OF CONFORMITY

UK CA 0120

Manufacturer

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

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

Product Type	:	**Anaesthesia workstation, general-purpose**
Product Identification	:	**Prima 465** *(See Appendix A for list of Catalog number)*
Basic UDI-DI	:	Refer Appendix A
Device Classification, Rule	:	Class IIb, Rule 11
Conformity Assessment Route	:	Part II of The Medical Devices Regulations 2002, Annex II excluding section 4 [as modified by Part 2 of Schedule 2A to The Medical Devices Regulations 2002]
Approved Body Name	:	SGS United Kingdom
Approved Body Number	:	0120
Certificate Number and Date	:	GB23/00000206, Issue: 25 Jan 2024, Valid until: 13 Jan 2029

Penlon Limited declares that the above-mentioned product(s) meet the provisions of the **Medical Devices Regulations 2002 (SI 618, as amended)**. The product has been subjected to conformity assessment procedures set out in the Medical Devices Regulations 2002. All supporting documentation is retained on the premises of the manufacturer.

Place and Date of Issue: Abingdon, 15 October 2024

Signed by:

SIGNATURE

Daniel Harrison

PRINT NAME

QARA Manager

POSITION

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

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Appendix A: Product Identification

Catalogue / Reference	Model (Product Name) / Version (Product Descriptions)	Basic UDI-DI	GMDN
5011301	Prima 465 Anaesthesia Machine	5051977ANM-PRI465JZ	37710