

UKCA Certificate - Full Quality Assurance System

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]

No.

UKCA 794574

Issued To:

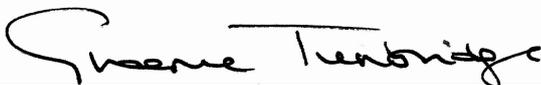
**Mediplus Ltd
Unit 7, The Gateway Centre
Coronation Road
Cressex Business Park
High Wycombe
HP12 3SU
United Kingdom**

In respect of:

See certificate scope page.

On the basis of our examination of the quality assurance system under the requirements of Part II of the Medical Devices Regulations 2002, Annex II excluding Section 4 [as modified by Part II of Schedule 2A to The Medical Devices Regulations 2002]. The quality assurance system meets the requirements of the regulation. For the placing on the market of class III products an Annex II (modified as described above) Section 4 certificate is required.

For and on behalf of BSI, an Approved Body for the above Regulation (Approved Body Number 0086):



Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

First Issued: **2023-10-17**

Date: **2024-10-04**

Expiry Date: **2029-10-17**

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Certificate No: UKCA 794574

Certificate Scope:

The design, development and final inspection of:

- **Sterile and non-sterile rectal catheters for use in urodynamics**
- **Sterile bladder catheters, for use in urology and urodynamics**
- **Sterile and non-sterile administration sets, for use in urology, urodynamics and theatres**
- **Sterile total intravenous anaesthesia (TIVA) sets, extension sets and peripheral connectors, for use within anaesthesiology, surgery, recovery and obstetrics**
- **Non-sterile Oxygen masks and Capnomasks, for oxygen delivery and monitoring of end tidal carbon dioxide**
- **Non-sterile silicone shelf pessary, for use in gynaecology**

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Page 2 of 3

Validity of this certificate is conditional on the quality system being maintained to the requirements of the regulation as demonstrated through the required surveillance activities of the Approved Body.

This certificate was issued electronically and is bound by the conditions of the contract.

Approved Body Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes, MK5 8PP, UK. Tel: + 44 845 080 9000

Corporate Contact: BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London, W4 4AL, UK.

A member of BSI Group of Companies.

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Supplementary Information to UKCA 794574

Issued To:

Mediplus Ltd
Unit 7, The Gateway Centre
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High Wycombe
HP12 3SU
United Kingdom

Device code	Device name	Intended purpose per IFU
Class IIb		
MD 0102	Bladder catheters	For urology
MD 0106	Silicone shelf pessaries	For prolapse and incontinence
Class IIa		
MD 0101	Oxygen masks and Capnomasks	---
MD 0102	Rectal catheters	---
	Bladder catheters	---
	Urology, urodynamics & theatre administration sets	---
	Sterile total intravenous anaesthesia (TIVA) sets, extension sets and peripheral connectors	---

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