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By Royal Charter

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. **CE 674211**

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 Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2018-01-08** Date: **2021-01-07** Expiry Date: **2024-05-26**

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Certificate No: CE 674211

Certificate Scope:

The design, development and manufacture 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;
Sterile vascular ligation/occlusion loops, for use in surgery;
Oxygen masks and Capnomasks, for oxygen delivery and monitoring of end tidal carbon dioxide;
Non-sterile Silicone Shelf Pessary, for use in gynaecology;
Sterile Silicone, 3 way catheter, for use in urology.

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Supplementary Information to CE 674211

Issued To:

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High Wycombe
HP12 3SU
United Kingdom

Number	Device Name	Intended purpose per IFU
Class IIa		
MD 0101	Oxygen masks and Capnomasks	N/A for class IIa devices
MD 0102	Rectal Catheters	
	Bladder catheters	
	Urology, urodynamics & theatre administration sets	
	Sterile total intravenous anaesthesia (TIVA) sets, extension sets and peripheral connectors	
	Silicone 3 way urology catheter	
MD 0106	Vascular ligation / occlusion loops	
Class IIb		
MD 0102	Bladder catheters	For urology
MD 0106	Silicone shelf pessaries	For prolapse and incontinence

First Issued: **2018-01-08** Date: **2021-01-07** Expiry Date: **2024-05-26**

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