



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, Senior Vice President Medical Devices

First Issued: **2018-01-08**

Date: **2021-01-07**

Expiry Date: **2024-05-26**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.
This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780
BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.
A member of BSI Group of Companies.

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

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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

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