By Royal Charter

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 772420**

Issued To: **DYSIS Medical Limited**
Gyleview House
3 Redheughs Rigg
Edinburgh
EH12 9DQ
United Kingdom

In respect of:

Design, manufacture and final inspection of digital colposcopy device for quantified mapping of the aceto-whitening effect on the vagina, cervix and external genitalia.
Those aspects of Annex II relating to securing and maintaining sterility of the sterile single use specula and of the sterile single use disposable treatment pipe.

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 Medical Devices

First Issued: **2022-06-29** Date: **2022-06-29** Expiry Date: **2027-06-28**

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Supplementary Information to UKCA 772420

Issued To:

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Device Code	Device Name	Intended purpose per IFU
Class IIa		
MD 1202	Digital Colposcope	N/A for class IIa devices
Class Is		
MD 0106	Specula	N/A for class Is devices
MD 0106	Treatment pipe	N/A for class Is devices

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List of Critical Subcontractors and Crucial Suppliers

Recognised as being involved in services related to the products covered by:

Certificate No:	**UKCA 772420**
Date:	**2022-06-29**
Issued To:	**DYSIS Medical Limited** **Gyleview House** **3 Redheughs Rigg** **Edinburgh** **EH12 9DQ** **United Kingdom**

Subcontractor:	**Service(s) supplied**
Andersen Caledonia Limited Caledonian House Phoenix Crescent Strathclyde Business Park Lanarkshire Bellshill ML4 3NJ United Kingdom	**ETO Sterilization**
Europlaz Technologies Ltd The Maltings Industrial Estate Hall Road Southminster CM0 7EQ UK	**Manufacture**
Sanmina-SCI AB Svedjevagen 12 Sjalevad 894 35 Sweden	**Design** **Manufacture**

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Subcontractor:	**Service(s) supplied**
Surtex Instruments Ltd. Kingspark Business Centre, Unit 202, 152-178 Kingston Road, New Malden KT3 3ST United Kingdom	**Manufacture**

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UKCA Certificate - Full Quality Assurance System Certificate History

Certificate No: **UKCA 772420**
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3 Redheughs Rigg
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Date	Reference Number	Action
Current	3697226	Issued – Traceable to CE 584854 Amended - removed subcontractor Sanmina Corporation
Current	3718049	Re-issued – Certificate renewal

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