By Royal Charter

EC Certificate - Full Quality Assurance System

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

No. **CE 584854**

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

In respect of:

The design and manufacture 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 in the design and manufacture 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 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: **2012-07-02** Date: **2021-04-15** Expiry Date: **2022-07-01**

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Supplementary Information to CE 584854

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

First Issued: **2012-07-02** Date: **2021-04-15** Expiry Date: **2022-07-01**

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List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

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Date:	**2021-04-15**
Issued To:	**DYSIS Medical Limited** **Gyleview House** **3 Redheughs Rigg** **Edinburgh** **EH12 9DQ** **United Kingdom**

Subcontractor:	**Service(s) supplied**
Anderson Caledonia Limited Caledonian House Phoenix Crescent Strathclyde Business Park North Lanarkshire Scotland ML4 3NJ United Kingdom	**ETO Sterilization**
DYSIS Medical Manolis Papagiannakis Leof Dimokratias 4-6, Neo Psychiko 15451, Greece	**EU Representative**
Europlaz Technologies Ltd The Maltings Industrial Estate Hall Road Southminster CM0 7EQ UK	**Manufacture**

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Subcontractor:	**Service(s) supplied**
Sanmina Corporation 13000 South Memorial Parkway, Huntsville Alabama 35803 USA	**Manufacture**
Sanmina-SCI AB Svedjevagen 12 Sjalevad 894 35 Sweden	**Design** **Manufacture**
Surtex Instruments Ltd. Kingspark Business Centre, Unit 202, 152-178 Kingston Road, New Malden KT3 3ST United Kingdom	**Manufacture**

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EC Certificate - Full Quality Assurance System Certificate History

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Date: **2021-04-15**
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Date	Reference Number	Action
02 July 2012	7806173	First issue.
04 August 2014	8134668	Change of scope adding "including sterile and non-sterile specula". Addition of subcontractor Europlaz Technologies Ltd for "Sterile Manufacture".
30 April 2015	8333446	Removal of subcontractor DySIS Medical Hellas.
03 October 2016	8575902	Addition of subcontractor Fearsom UK Ltd (t/a Fearsome) for Design. Change of address of the legal manufacturer from Alba Innovation Centre, Livingston, EH54 7GA to Westpoint, 4 Redheughs Rigg, Edinburgh EH12 9DQ. Change of scope from "The design and manufacture of digital colposcopy devices for quantified mapping of the aceto-whitening effect on the vagina, cervix and external genitalia, including sterile and non-sterile specula. " to reflect the reclassification of the specula.

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Date	Reference Number	Action
16 June 2017	8747443	Renewal. Change of address from DYSIS Medical Limited, Westpoint, 4 Redheughs Rigg, Edinburgh, EH12 9DQ to DYSIS Medical Limited, Gyleview House, 3 Redheughs Rigg, Edinburgh, EH12 9DQ. Addition of service supplied "Control of Sterilization" for subcontractor Europlaz Technologies Ltd. Addition of subcontractor Andersen Caledonia Ltd for "Sterilization". Addition of subcontractor Sanmina-SCI AB for "Design and Manufacture". Change of scope to include DYSIS Disposable Treatment Pipe.
21 February 2021	8003242	Traceable to NB 0086.

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Date	Reference Number	Action
Current	3253300	Addition of subcontractors: Surtex Instruments Limited and Sanmina Corporation Addition of EU Representative: DYSIS Medical, Manolis Papagiannakis, Leof Dimokratias 4-6, Neo Psychiko 15451, Greece Removal of subcontractors: - RB Medical Engineering Ltd Alton Road Industrial Estate, Ross on Wye, Herefordshire, HR9 5NS - Fearsom UK Ltd (t/a Fearsome) The Whisky Bond 2 Dawson Road, Glasgow, G4 9SS Scotland - Integrated Technologies Ltd Viking House Elingham Way Ashford, Kent TN23 6NF United Kingdom Addition of device table.