By Royal Charter

EC Certificate - Full Quality Assurance System

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

No. **CE 576378**

Issued To: **Sterilucent, Inc.**
1400 Marshall Street NE
Minneapolis
Minnesota
55413
USA

In respect of:

The design and manufacture of hydrogen peroxide sterilizers and sterilant.

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 0086):

Stewart Brain, Head of Compliance & Risk - Medical Devices

First Issued: **2014-03-06** Date: **2019-02-28** Expiry Date: **2024-03-05**

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Supplementary Information to CE 576378

Issued To:

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NBOG code(s)	Device description	Intended purpose
Class IIb		
MD 1107	Hydrogen peroxide gas sterilizer	Sterilization (disinfection) of reusable invasive medical devices
MD 0108	Hydrogen peroxide device sterilant	Sterilization (disinfection) of reusable invasive medical devices

First Issued: **2014-03-06** Date: **2019-02-28** Expiry Date: **2024-03-05**

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List of Significant Subcontractors

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

Certificate No:	**CE 576378**
Date:	**2019-02-28**
Issued To:	**Sterilucent, Inc.** **1400 Marshall Street NE** **Minneapolis** **Minnesota** **55413** **USA**

Subcontractor:	**Service(s) supplied**
Medical Device Safety Service (MDSS) Gmbh Schiffgraben 41 D-30175 Hannover Germany	**EU Representative**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 576378**

Date: **2019-02-28**

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Date	Reference Number	Action
06 March 2014	8063071	First issue
Current	9681642	Renewal. Addition of device table.