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 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2014-03-06** Date: **2020-07-13** Expiry Date: **2024-03-05**

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Supplementary Information to CE 576378

Issued To:

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1400 Marshall Street NE
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Number	Device Name	Intended purpose per IFU
Class IIb		
MD 1107	HC 80TT Vaporized Hydrogen Peroxide Sterilizer - Vaporized hydrogen peroxide sterilizer	Sterilization (disinfection) of reusable invasive medical devices
MD 0108	Sterilucent Sterilant Disc - Hydrogen peroxide device sterilant	Sterilization (disinfection) of reusable invasive medical devices

First Issued: **2014-03-06** Date: **2020-07-13** Expiry Date: **2024-03-05**

By Royal Charter

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

List of Significant Subcontractors

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

Certificate No:	**CE 576378**
Date:	**2020-07-13**
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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By Royal Charter

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 576378**

Date: **2020-07-13**

Issued To: **Sterilucent, Inc.**
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Date	Reference Number	Action
06 March 2014	8063071	First issue
28 February 2019	9681642	Renewal. Addition of device table
04 March 2019	7782368	Traceable to NB 0086
Current	3168844	Addition of device "HC 80TT Vaporized Hydrogen Peroxide Sterilizer". Removal of the device "PSD-85 Vaporized Hydrogen Peroxide Sterilizer".

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