

# EC Certificate - Full Quality Assurance System

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

**No.** CE 576378  
**Issued To:** Steriluent, 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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Page 1 of 2

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.

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## Supplementary Information to CE 576378

Issued To:

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

| Number           | Device Name   | Intended purpose per IFU  |
|------------------|---|---|
| <b>Class IIb</b> |   |   |
| 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 |

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Page 2 of 2

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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.

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## List of Significant Subcontractors

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

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**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: **2020-07-13**  
 Issued To: **Sterilucent, Inc.**  
**1400 Marshall Street NE**  
**Minneapolis**  
**Minnesota**  
**55413**  
**USA**

| 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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Page 1 of 1

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