# EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

**No.** **CE 98334**

Issued To: **Chemence Medical, Inc.**
**200 Technology Drive**
**Alpharetta**
**Georgia**
**30005**
**USA**

In respect of:

**The manufacture and final release of sterile medical adhesives for external use.**

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III 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: **2006-04-10** Date: **2021-03-09** Expiry Date: **2024-05-26**

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**Supplementary Information to CE 98334**

Issued To:

**Chemence Medical, Inc.**
**200 Technology Drive**
**Alpharetta**
**Georgia**
**30005**
**USA**

| Device code | Device name | Intended purpose per IFU |
|---|---|---|
| **Class IIa** | | |
| MD 0303 | Sterile medical adhesives | --- |

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By Royal Charter

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# List of Significant Subcontractors

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

| | |
|---|---|
| Certificate No: | **CE 98334** |
| Date: | **2021-03-09** |
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| **Subcontractor:** | **Service(s) supplied** |
|---|---|
| Atlantico Systems<br>34 Oldfield<br>Kingston<br>Galway<br>Ireland | **EU Representative** |

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# EC Certificate - Production Quality Assurance Certificate History

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**Georgia**
**30005**
**USA**

| Date | Reference Number | Action |
|---|---|---|
| 10 April 2006 | | First Issue. |
| 26 April 2006 | | Correct to company name to read Chemence Medical Products, Inc. |
| 25 May 2011 | 7686376 | Certificate renewal: scope clarification and addition of EU representative to subcontractor list. |
| 31 July 2013 | 7990378 | Change of address for 185 Bluegrass Valley Parkway to 200 Technology Drive. |
| 08 April 2016 | 8499935 | Certificate renewal. Change of company name to Chemence Medical, Inc. |
| 11 March 2019 | 7781262 | Traceable to NB 0086. |
| 09 March 2020 | 9783582 | Update the EU Representative and remove the subcontractor "Professional Contract Sterilization Inc" |

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| Date | Reference Number | Action |
|---|---|---|
| Current | 3391276 | Certificate renewal.<br>Removal of sealing devices from certificate scope.<br>Addition of supplementary information table. |