

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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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.

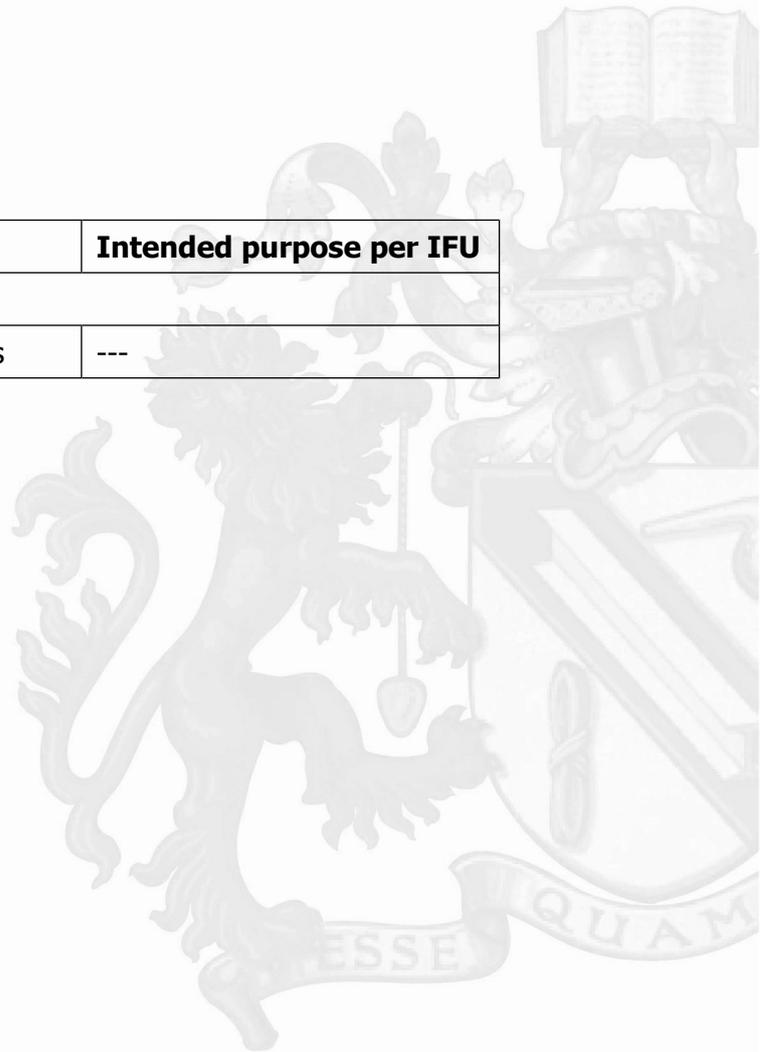
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Supplementary Information to CE 98334

Issued To:

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



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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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Subcontractor:

Service(s) supplied

Atlantico Systems
34 Oldfield
Kingston
Galway
Ireland

EU Representative

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Certificate History

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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. Removal of sealing devices from certificate scope. Addition of supplementary information table.