



EC Certificate - Production Quality Assurance

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

No. Issued To: CE 502193 Centurion Medical Products Corporation 100 Centurion Way Williamston Michigan 48895 USA

In respect of:

Those aspects of Annex V relating to securing and maintaining sterility by ethylene oxide in the manufacture of sterile dressings and securement devices.

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 C Stade

Gary E Slack, Senior Vice President Medical Devices

First Issued: 2006-03-24

Date: 2021-01-20

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.

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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Supplementary Information to CE 502193

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NBOG code(s)	Device description	Intended purpose
Class I Sterile		She have been
MD 0301	Sterile Dressings	NA for Class I Sterile devices
	Vascular Access Dressings / Securement Devices	

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