

EC Certificate - Full Quality Assurance System

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

No. CE 612363
Issued To: **Aspen Surgical Products Inc.**
6945 Southbelt Drive, SE
Caledonia
Michigan
49316
USA

In respect of:

The design, development and manufacture of sterile Surgical Needles and Endoscopic Fog Inhibitors and sterile and non-sterile Suture Boots, Vessel Loops and Silicone Vessel Loops.

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: **2014-04-24**

Date: **2021-05-05**

Expiry Date: **2023-08-16**

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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 612363

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6945 Southbelt Drive, SE
Caledonia
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49316
USA**

Number	Device Name	Intended purpose per IFU
Class IIa		
MD 0106	Surgical Needles (sterile)	---
MD 0106	Endoscopic fog inhibitors (sterile)	---
MD 0106	Suture boots (sterile)	---
MD 0106	Suture boots (non-sterile)	---
MD 0106	Vessel loops (sterile)	---
MD 0106	Vessel loops (non-sterile)	---
MD 0106	Silicone vessel loops (sterile)	---
MD 0106	Silicone vessel loops (non-sterile)	---

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