

EC Certificate - Production Quality Assurance

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

No. CE 612364
Issued To: **Aspen Surgical Products Inc.**
6945 Southbelt Drive, SE
Caledonia
Michigan
49316
USA

In respect of:

Those aspects of manufacture concerned with securing and maintaining sterility of sterile Cautery Tip Cleaners, Wound Closures and Surgical Light Handle and Camera Covers.

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: **2014-04-24**

Date: **2021-04-27**

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 612364

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Number	Device Name	Intended purpose per IFU
Class Is		
MD 0108	Cautery Tip Cleaners	---
MD 0301	Wound Closures	---
MD 0106	Surgical Light Handle Covers	---
MD 0106	Surgical Camera Covers	---

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