



EC Certificate - Production Quality Assurance

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

No.**CE 571159**

Issued To:

**Aspen Surgical Products Inc.
6945 Southbelt Drive, SE
Caledonia
Michigan
49316
USA**

In respect of:

The manufacture and final inspection of sterile and non-sterile surgical blades and surgical scalpels.**Those aspects of Annex V concerned with securing and maintaining sterile conditions of surgical marking pens, scalpel handles and scalpel handle 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 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: **2011-11-14**Date: **2020-10-14**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 571159

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Number	Device Name	Intended purpose per IFU
Class IIa		
MD 0106	Sterile Surgical Scalpels	---
MD 0106	Non-sterile Surgical Scalpels	---
MD 0106	Sterile Surgical Blades	---
MD 0106	Non-sterile Surgical Blades	---
Class Is		
MD 0106	Surgical Marking Pens	---
MD 0106	Scalpel Handles	---
MD 0106	Scalpel Handle Covers	---

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