By Royal Charter

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 Silver Wound Dressings, Chitosan Wound Dressing, Surgical Needles, Endoscopic Fog Inhibitors, Endoscopic Kittners, Wound Drains, Suture Boots and Vessel Loops and sterile and non-sterile Silicone Vessel Loops, Clamp Covers, Surgical Probes and Film and Alginate wound dressings, Epidural Needles, Laparoscopic Needle kits with Catheters, Collection Needles, Stylet Needles and Ophthalmic Cannula

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):

Albert Roossien, Regulatory Lead

First Issued: **2014-04-24** Date: **2019-01-03** Expiry Date: **2023-08-16**

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