

EC Certificate - Full Quality Assurance System

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

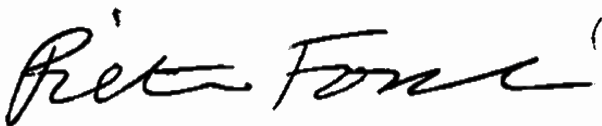
No. CE 607775
Issued To: **ASEPTICO INC.**
8333 216th Street SE
Woodinville
Washington
98072
USA

In respect of:

**Design, development and manufacture of dental products including:
powered dental drills, gutta percha delivery systems, portable dental
units and orthodontic appliances**

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 0086):



Pietro Foschi - Strategic Delivery Director

First Issued: **07 May 2014**

Date: **01 December 2014**

Expiry Date: **01 December 2019**

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

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 607775**
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8333 216th Street SE
Woodinville
Washington
98072
USA**

Subcontractor:

Service(s) supplied

Advena Ltd
Pure Offices
Plato Close
Warwick CV34 6WE
United Kingdom

EU Representative

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 607775**
Date: **01 December 2014**
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8333 216th Street SE
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USA**

Date	Reference Number	Action
07 May 2014	8077477	First Issue, Transfer from LNE Certificate No. 11998 rev 2
01 December 2014	8255013	Certificate Renewal

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