

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 and portable dental units

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: **2014-05-07**

Date: **2020-06-24**

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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List of Significant Subcontractors

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

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Subcontractor:

Service(s) supplied

Advena Ltd
Tower Business Centre, 2nd Flr,
Tower Street, Swatar, BKR 4013
Malta

EU Representative

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 607775**
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Date	Reference Number	Action
07 May 2014	8077477	First Issue, Transfer from LNE Certificate No. 11998 rev 2.
01 December 2014	8255013	Certificate Renewal.
27 February 2019	8077483	Traceable to NB 0086.
23 March 2020	3164761	Certificate Renewal. Removal of "orthodontic appliances" from the scope.
Current	3224577	Change of EU Representative from Advena (UK) to Advena (Malta).

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This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

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