

# EC Certificate - Full Quality Assurance System

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

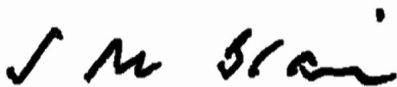
**No.** CE 666283  
**Issued To:** **Katena Products, Inc.**  
**4 Stewart Court**  
**Denville**  
**New Jersey**  
**07834**  
**USA**

In respect of:

**Design and manufacture of sterile ophthalmic Punctum Plugs, Flow Controllers and accessories**

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):



Stewart Brain, Head of Compliance & Risk -  
Medical Devices

First Issued: **2017-12-21**

Date: **2017-12-21**

Expiry Date: **2022-12-20**

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Page 1 of 1

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:

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**07834**  
**USA**

<b>Subcontractor:</b>	<b>Service(s) supplied</b>
Advena Limited Pure Offices Plato Close Warwick CV34 6WE United Kingdom	<b>EU Representative</b>
Enteroptyx OEM 8500 Wolf Lake Dr. Suite 110 Memphis Tennessee 38133 USA	<b>Manufacture</b>
NuPak Medical Ltd 11849 Starcrest Drive San Antonio Texas 78247 USA	<b>Manufacture Packaging</b>

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**07834**  
**USA**

**Subcontractor:**

**Service(s) supplied**

Sterigenics  
3125 Wichita Court  
Fort Worth  
Texas  
76140  
USA

**Gamma Sterilization**

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# EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 666283**  
 Date: **2017-12-21**  
 Issued To: **Katena Products, Inc.**  
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**USA**

Date	Reference Number	Action
Current	8661056	First Issue.



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