

# EC Certificate - Production Quality Assurance

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

**No.** CE 666284  
**Issued To:** **Katena Products, Inc.**  
**4 Stewart Court**  
**Denville**  
**New Jersey**  
**07834**  
**USA**

In respect of:

**The manufacture and final inspection of sterile single use disposable cannula and other disposable hand held surgical instruments for use in ophthalmic surgery**  
**Those aspects of Annex V concerned with securing and maintaining the sterility in the manufacture of sterile disposable ophthalmic sponge products**

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 the placing on the market of class IIb and class III products an Annex III 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: **2017-07-13**Date: **2017-09-28**Expiry Date: **2022-07-12**

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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:

Certificate No: **CE 666284**  
Date: **2017-09-28**  
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**USA**

<b>Subcontractor:</b>	<b>Service(s) supplied</b>
Advena Ltd Pure Offices Plato Close Warwick CV34 6WE United Kingdom	<b>EU Representative</b>
Anodyne Surgical 804 Corporate Centre Drive O'Fallon Missouri 63368 USA	<b>Control of Sterilization Finished Device Supplier</b>
Hurricane Medical 5315 Lena Road Bradenton Florida 34211-9442 USA	<b>Control of Sterilization Finished Device Supplier</b>

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**USA**

<b>Subcontractor:</b>	<b>Service(s) supplied</b>
Isomedix Operations, Inc. 1000 S. Sarah Place Ontario California 91761 USA	<b>Gamma Sterilization</b>
Isomedix Operations, Inc. 2500 Commerce Drive Libertyville Illinois 60048 USA	<b>Gamma Sterilization</b>
Network Medical Products, Inc. 183 Providence New London Turnpike North Stonington Connecticut 06359 USA	<b>Control of Sterilization</b> <b>Finished Device Supplier</b>

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**USA**

**Subcontractor:**

**Service(s) supplied**

Sterigenics U.S., LLC  
502 Prairie Mine Rd  
Mulberry  
Florida  
33860  
USA

**Gamma Sterilization**

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# EC Certificate - Production Quality Assurance Certificate History

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Date	Reference Number	Action
13 July 2017	8661062	First issue.
Current	8791773	Scope extension to include disposable cannula and other hand held surgical instruments for ophthalmic surgery.  Addition of Anodyne Surgical and Isomedix Ops as significant s/cs for manufacture and sterilization respectively.