



By Royal Charter

EU Quality Assurance Certificate

Regulation (EU) 2017/745, Annex XI Part A

MDR 761643 R000

Manufacturer: Katena Products, Inc.

Address:

6 Campus Drive, Suite 310
Parsippany
New Jersey
07054
USA

Single Registration Number: US-MF-000020067

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex XI part A, the quality system meets the requirements of the Regulation. For the placing on the market of Class III and Class IIb devices an additional Annex X certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Medical Devices

First Issued: **2022-08-05**

Date: **2022-08-05**

Expiry Date: **2027-08-04**

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
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EU Authorised Representative: Advena Ltd

Address:

Tower Business Centre
2nd Floor
Tower Street
Swatar, BKR 4013
Malta

EU Authorised Representative: Emergo Europe B.V.

Address:

Prinsessegracht 20
2514 AP The Hague
The Netherlands



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Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Single use disposable Ophthalmic Cannulas, Cystotomes, Needles	Class IIa
Single use ophthalmic speculum	Class Is
Ophthalmic sponge	Class Is
Instrument wipe and corneal shield	Class Is
Single use ophthalmic lenses	Class Is
Single use lens forceps	Class Is
Single use lens ring	Class Is
General Surgery instruments, reusable	Class Ir
Sharp instruments, reusable	Class Ir
Suture instruments, reusable	Class Ir
ENT instruments, reusable	Class Ir
Microsurgery instruments, reusable	Class Ir
Ophthalmology instruments, reusable	Class Ir
Ophthalmology reusable measuring gauges and callipers	Class Ir & Im

For Class Is devices, the Notified Body conformity assessment is limited to the aspects relating to establishing, securing and maintaining sterile conditions.

For Class Im devices, the Notified Body conformity assessment is limited to the aspects relating to the conformity of the devices with the metrological requirements.

For Class Ir devices (Class I re-usable surgical instruments), the Notified Body conformity assessment is limited to the aspects relating to the reuse of the device.

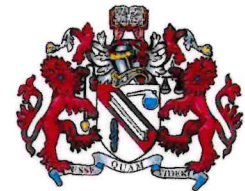
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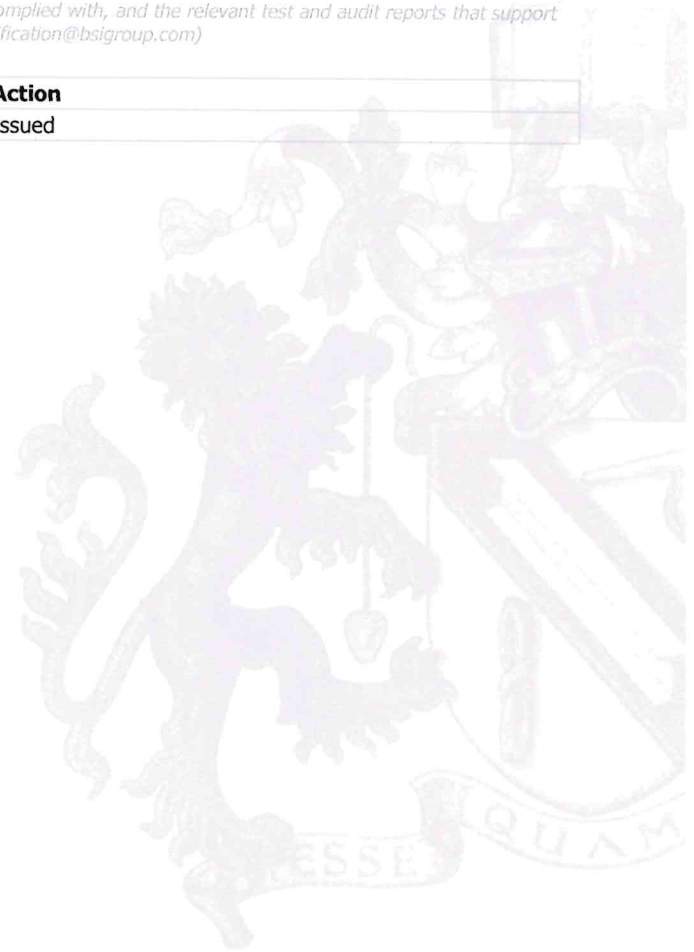
Regulation (EU) 2017/745, Annex XI Part A

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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
Current	3563219	Issued



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