

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that: **Katena Products, Inc.**
6 Campus Drive, Suite 310
Parsippany
New Jersey
07054
USA

Facility ID Number: F000250

Holds Certificate No: **MDSAP 687322**

The company listed on this certificate has been audited to and found to conform with ISO 13485:2016 including the following country specific requirements:

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure

Brazil: RDC ANVISA n. 67/2009, RDC ANVISA n. 665/2022 - Good Manufacturing Practices, RDC ANVISA n. 551/2021

Canada: Medical Devices Regulations - Part 1 - SOR 98/282

Japan: MHLW MO No 169 (2004), as amended by MHLW MO No 60 (2021), PMD Act

USA: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

Design, manufacture and inspection of ophthalmic implants and medical devices (Sterile lens and reusable lens). Design, manufacture, inspection and repair of reusable ophthalmic surgical instruments. Manufacture and inspection of sterile ophthalmic surgical instruments and sterile sponge.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2019-02-11

Effective Date: 2024-05-03

Expiry Date: 2027-05-02



BSI Group America Inc. is an MDSAP recognised auditing organization

Certificate No: **MDSAP 687322**

Location	Registered Activities
Katena Products, Inc. 6 Campus Drive, Suite 310 Parsippany New Jersey 07054 USA Facility ID Number: F000250	Customer Service, Marketing, Purchasing, Finance, Executive Management.
Katena Products, Inc. 4 Middlebury Boulevard, Unit #1 Randolph, New Jersey 07869 USA Facility ID Number: F000250	Manufacturing, Inspection, Packaging/Labeling, Storage, Distribution, Repair/Service, QA/RA, Engineering/Design.



Original Registration Date: 2019-02-11 Effective Date: 2024-05-03 Expiry Date: 2027-05-02

This certificate remains the property of BSI and shall be returned immediately upon request.
An electronic certificate can be authenticated [online](#). Printed copies can be validated at www.bsigroup.com/ClientDirectory
To be read in conjunction with the scope above or the attached appendix.

Americas Headquarters: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA
A Member of the BSI Group of Companies.