



Certificate No. 3978-1-2022

CERTIFICATE TO FOREIGN GOVERNMENT

In order to allow the importation of United States products into foreign countries, the U.S. Food and Drug Administration (FDA) certifies the following information concerning the product(s) to be exported listed below:

Name of Product(s)

See Attached List

(Two Pages)

Name of Manufacturer/Distributor, Address

See Attached List

(One Page)

The product(s) described above (and the manufacturing/distribution site(s) which produces/distributes it) is subject to the jurisdiction of the FDA under the Federal Food, Drug, and Cosmetic Act.

It is certified that the above product(s) may be marketed in, and legally exported from, the United States of America at this time. The manufacturing plant(s) in which the product(s) is produced is subject to periodic inspections. The last such inspection showed that the plant(s), at that time, appeared to be in substantial compliance with current good manufacturing practice requirements for the product(s) listed above.

Sincerely,

CDR Cesar A. Perez, PhD, Director
DRP2: Division of Establishment Support
Office of Regulatory Programs
Office of Product Evaluation and Quality
Center for Devices and Radiological Health
U.S. Food and Drug Administration, DHHS

This certificate is valid from January 24, 2022 to January 23, 2024.





Certificate No. 3978-1-2022

Certificate to Foreign Government - Name of Manufacturer/Distributor Attachment Page 1 of 1

Name of Corporate Headquarters

KATENA PRODUCTS, INC.
6 CAMPUS DRIVE
SUITE 310
Parsippany, NJ
USA 07054

Name of Manufacturer/Distributor

KATENA PRODUCTS, INC.
4 Middlebury Boulevard
Unit #1
Randolph, NJ
USA 07869

---END OF MANUFACTURER/DISTRIBUTOR LIST---





Certificate No. 3978-1-2022

Certificate to Foreign Government - Name of Product(s) Attachment Page 1 of 2

Name of Corporate Headquarters

KATENA PRODUCTS, INC.
6 CAMPUS DRIVE
SUITE 310
Parsippany, NJ
USA 07054

Name of Manufacturer/Distributor

KATENA PRODUCTS, INC.
4 Middlebury Boulevard
Unit #1
Randolph, NJ
USA 07869

Name of Product(s)

K30-1000 3 MIRROR LENS, BOX OF 10
K30-1002 SMALL 3 MIRROR LENS, BOX OF 10
K30-1005 4 MIRROR LENS, BOX OF 10
K30-1010 4 MIRROR GONIO LENS WITH HANDLE, BOX OF 10
K30-1015 SINGLE MIRROR LENS, BOX OF 10
K30-1020 SINGLE MIRROR LENS WITH HANDLE BOX OF 10
K30-1110 FUNDUS LENS, BOX OF 10
K30-1120 CAPSULOTOMY LENS, BOX OF 10
K30-1130 IRIDOTOMY LENS, BOX OF 10
K30-1210 SUTURE LYSIS LENS, BOX OF 10
K30-1300 RETINA 180 LENS, BOX OF 10
K30-1310 RETINA 170 LENS, BOX OF 10
K30-1315 RETINA 130 LENS, BOX OF 10
K30-1320 RETINA 90 LENS, BOX OF 10
K30-1330 RETINA 200 LENS, BOX OF 10
K30-1400 SURGICAL GONIO PRISM, RIGHT HAND, BOX OF 10
K30-1405 SURGICAL GONIO PRISM, LEFT HAND, BOX OF 10
K30-1407 HANDS-FREE GONIO LENS, BOX OF 10
K30-1420 20 DEGREE PRISM LENS, BOX OF 10
K30-1425 30 DEGREE PRISM LENS, BOX OF 10
K30-1430 BI-CONCAVE LENS, BOX OF 10
K30-1435 MAGNIFIER LENS, BOX OF 10
K30-1440 PLANO LENS, BOX OF 10
K30-1450 SURGICAL WIDE FIELD LENS, BOX OF 10
K30-1505 LENS HOLDING FORCEPS, BOX OF 10
K30-1520 SURGICAL WIDE FIELD LENS WITH HANDLE, BOX OF 10
K30-1530 SUTURE RING, BOX OF 10
K30-1535 SUTURE RING WITH TABS, BOX OF 10
K30-2400 90D LENS, BOX OF 10
K30-2405 OSHER 78D LENS, BOX OF 10
K30-2410 60D LENS, BOX OF 10
K30-2415 28D LENS, BOX OF 10
K30-2420 20D LENS, BOX OF 10
K31-1002 3 MIRROR DIAMOND REUSABLE LENS
K31-1005 4 MIRROR DIAMOND REUSABLE LENS
K31-1120 DIAMOND CAPSULOTOMY LENS
K31-1130 DIAMOND IRIDOTOMY LENS
K31-1330 RETINA 200 DIAMOND REUSABLE LENS
K31-2350 90D DIAMOND LENS REUSABLE
K31-2355 78D DIAMOND LENS REUSABLE
K31-2360 60D DIAMOND LENS REUSABLE
K31-2365 28D DIAMOND LENS REUSABLE
K31-2370 20D DIAMOND LENS REUSABLE





Certificate No. 3978-1-2022

Certificate to Foreign Government - Name of Product(s) Attachment Page 2 of 2

K31-4000 LENS PROTECTIVE CASE (2-LENS)

K31-4005 LENS PROTECTIVE CASE (3-LENS)

K31-4010 LENS PROTECTIVE CASE (8-LENS)

-----END OF PRODUCT LIST-----

