



**U.S. FOOD & DRUG
ADMINISTRATION**

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Certificate No. 4392-1-2019

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

(Five Pages)

Name of Manufacturer/Distributor, Address

Name of Manufacturer

UNIQUE TECHNOLOGIES, INC.

111 Chestnut St

Mohnton, PA USA 19540

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 device product(s) may be marketed in, and legally exported from, the United States of America at this time. While the manufacturing plant(s) in which the device product(s) is produced is subject to inspection, FDA does not routinely inspect manufacturing firms that only make Class 1 medical devices. However, the firm has certified that it is currently operating in substantial compliance with current good manufacturing practice requirements for the device product(s) listed above.

CAPT Sean M. Boyd, MPH, USPHS
Deputy Director for Regulatory Affairs
Office of Compliance
Center for Devices and Radiological Health
U.S. Food and Drug Administration, DHHS

This certificate is valid from January 28, 2019 to January 27, 2021.





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Name of Manufacturer

UNIQUE TECHNOLOGIES, INC.
111 Chestnut St
Mohnton, PA USA 19540

Name of Product(s)

UniqueEdge® Microsurgical Knives

Clear Corneal Knives

- 52-2563 2.5 mm Clear Corneal Knife, Angled
- 52-2635 2.65 mm SC Clear Corneal Knife, Angled
- 52-2663 2.65 mm Clear Corneal Knife, Angled
- 52-2735 2.75 mm SC Clear Corneal Knife, Angled
- 52-2763 2.75 mm Clear Corneal Knife, Angled
- 52-2835 2.85 mm SC Clear Corneal Knife, Angled
- 52-2863 2.85 mm Clear Corneal Knife, Angled
- 52-3035 3.0 mm SC Clear Corneal Knife, Angled
- 52-3063 3.0 mm Clear Corneal Knife, Angled
- 52-3235 3.2 mm SC Clear Corneal Knife, Angled
- 52-3263 3.2 mm Clear Corneal Knife, Angled

UniBevel Clear Corneal Knives

- 52-2242 2.2 mm UniBevel Clear Corneal Knife, Angled
- 52-2442 2.4 mm UniBevel Clear Corneal Knife, Angled
- 52-2542 2.5 mm UniBevel Clear Corneal Knife, Angled
- 52-2642 2.65 mm UniBevel Clear Corneal Knife, Angled
- 52-2742 2.75 mm UniBevel Clear Corneal Knife, Angled
- 52-2842 2.85 mm UniBevel Clear Corneal Knife, Angled
- 52-3042 3.0 mm UniBevel Clear Corneal Knife, Angled
- 52-3242 3.2 mm UniBevel Clear Corneal Knife, Angled

Crescent Knives

- 54-1000 2.0 mm Crescent Knife, Straight
- 54-1010 2.0 mm Crescent Knife, Angled
- 54-1012 2.2 mm Crescent Knife, Angled
- 54-1013 2.3 mm Crescent Knife, Angled
- 54-1020 2.0 mm Crescent Knife, Angled, Bevel Down
- 54-1031 2.0 mm Crescent Knife, Angled, Double Bevel
- 54-1060 1.25 mm Mini Crescent Knife, Angled, Double Bevel

Disc/Spoon Knives

- 54-2261 2.2 mm Spoon Knife, Angled
- 54-3061 3.0 mm Spoon Knife, Angled

Implant Knives

- 56-3561 3.5 mm Implant Knife, Angled
- 56-4061 4.0 mm Implant Knife, Angled
- 56-5261 5.2 mm Implant Knife, Angled
- 56-5361 3.2 mm Implant Knife, Angled

Precision Depth Knives

- 52-0300 300 Micron Precision Depth Knife
- 52-0350 350 Micron Precision Depth Knife
- 52-0550 550 Micron Precision Depth Knife
- 52-0600 600 Micron Precision Depth Knife

MVR Sideport Knives

- 58-2008 0.8 mm (23G) MVR Sideport Knife, Angled
- 58-2010 1.0 mm MVR Sideport Knife, Angled
- 58-2011 1.1 mm MVR Sideport Knife, Angled
- 58-2012 1.2 mm (20G) MVR Sideport Knife, Angled
- 58-2014 1.4 mm (19G) MVR Sideport Knife, Angled
- 58-2015 1.5 mm MVR Sideport Knife, Angled
- 58-2308 0.8 mm (23G) MVR Sideport Knife, Straight
- 58-2311 1.1 mm MVR Sideport Knife, Straight





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58-2312 1.2 mm (20G) MVR Sideport Knife, Straight
58-2314 1.4 mm (19G) MVR Sideport Knife, Straight
58-3011 1.1mm AK Sideport Knife, Angled

Slit Knives

52-1463 1.4 mm MicroPhaco Slit Knife, Angled
52-1563 1.5 mm MicroPhaco Slit Knife, Angled
52-1863 1.8 mm MicroPhaco Slit Knife, Angled
52-2063 2.0 mm MicroPhaco Slit Knife, Angled
52-2261 2.2 mm MicroPhaco Slit Knife, Angled
52-2461 2.4 mm Slit Knife, Angled
52-2561 2.5 mm Slit Knife, Angled
52-2661 2.65 mm Slit Knife, Angled
52-2701 2.75 mm Slit Knife, Straight
52-2761 2.75 mm Slit Knife, Angled
52-2801 2.8 mm Slit Knife, Straight
52-2808 2.8 mm Slit Knife, Angled
52-2861 2.85 mm Slit Knife, Angled
52-2901 3.0 mm Slit Knife, Straight
52-2961 3.0 mm Slit Knife, Angled
52-3201 3.2 mm Slit Knife, Straight
52-3261 3.2 mm Slit Knife, Angled
52-3561 3.5 mm Slit Knife, Angled
52-5261 5.2 mm Slit Knife, Angled

Double Bevel Slit Knives

52-2263 2.2 mm CMP Knife, Angled, Double Bevel
52-2431 2.4 mm Slit Knife, Angled, Double Bevel
52-2531 2.5 mm Slit Knife, Angled, Double Bevel
52-2631 2.65 mm Slit Knife, Angled, Double Bevel
52-2731 2.75 mm Slit Knife, Angled, Double Bevel
52-2830 2.8 mm Slit Knife, Angled, Double Bevel
52-2831 2.85 mm Slit Knife, Angled, Double Bevel
52-2931 3.0 mm Slit Knife, Angled, Double Bevel
52-3231 3.2 mm Slit Knife, Angled, Double Bevel

AK Slit Knives

52-1252 1.2 mm Double Bevel AK Slit Knife, Angled
52-1852 1.8 mm Double Bevel AK Slit Knife, Angled
52-2250 2.2 mm AK MicroPhaco Slit Knife, Angled
52-2252 2.2 mm Double Bevel AK Slit Knife, Angled
52-2450 2.4 mm AK Slit Knife, Angled
52-2452 2.4 mm Double Bevel AK Slit Knife, Angled
52-2552 2.5 mm Double Bevel AK Slit Knife, Angled
52-2652 2.65 mm Double Bevel AK Slit Knife, Angled
52-2750 2.75 mm AK Slit Knife, Angled
52-2752 2.75 mm Double Bevel AK Slit Knife, Angled
52-2850 2.85 mm AK Slit Knife, Angled
52-2851 2.8 mm AK Slit Knife, Angled
52-3050 3.0 mm AK Slit Knife, Angled
52-3250 3.2 mm AK Slit Knife, Angled

UniBevel Slit Knives

52-1040 1.0 mm UniBevel Slit Knife, Angled
52-1240 1.2 mm UniBevel Slit Knife, Angled
52-1440 1.4 mm UniBevel Slit Knife, Angled
52-1640 1.6 mm UniBevel Slit Knife, Angled
52-1840 1.8 mm UniBevel Slit Knife, Angled
52-2040 2.0 mm UniBevel Slit Knife, Angled
52-2240 2.2 mm UniBevel Slit Knife, Angled
52-2440 2.4 mm UniBevel Slit Knife, Angled
52-2540 2.5 mm UniBevel Slit Knife, Angled





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52-2640 2.65 mm UniBevel Slit Knife, Angled
52-2740 2.75 mm UniBevel Slit Knife, Angled
52-2840 2.85 mm UniBevel Slit Knife, Angled
52-2848 2.8 mm UniBevel Slit Knife, Angled
52-3040 3.0 mm UniBevel Slit Knife, Angled
52-3240 3.2 mm UniBevel Slit Knife, Angled

Specialty Knives

58-5703 #57 Scleral Knife
58-6603 Lamellar Knife
58-6810 Needle Knife
58-6903 #69 Knife

Stab Knives

52-1501 15 Deg. Stab Knife
52-1531 15 Deg. 3 mm Restricted Depth Stab Knife
52-1551 15 Deg. 5 mm Restricted Depth Stab Knife
52-2201 22.5 Deg Stab Knife
52-2241 22.5 Deg. 4 mm Restricted Depth Stab Knife
52-3001 30 Deg Stab Knife
52-3036 30 Deg. 3.5 mm Restricted Depth Stab Knife
52-3051 30 Deg. 5 mm Restricted Depth Stab Knife
52-4501 45 Deg. Stab Knife

Trapezoid Knives

55-1214 1.2 x 1.4 mm Trapezoid Knife, Angled
55-1416 1.4 x 1.6 mm Trapezoid Knife, Angled
55-1517 1.5 x 1.7 mm Trapezoid Knife, Angled
55-1520 1.5 x 2.0 mm Trapezoid Knife, Angled
55-1618 1.6 x 1.8 mm Trapezoid Knife, Angled
55-1720 1.75 x 2.0 mm Trapezoid Knife, Angled
55-1822 1.8 x 2.2 mm Trapezoid Knife, Angled
55-2022 2.0 x 2.2 mm Trapezoid Knife, Angled
55-2522 2.5 x 2.9 mm Trapezoid Knife, Angled
55-2524 2.5 x 3.2 mm Trapezoid Knife, Angled
55-2723 2.75 x 3.0 mm Trapezoid Knife, Angled
55-2724 2.75 x 3.2 mm Trapezoid Knife, Angled
55-2824 2.85 x 3.2 mm Trapezoid Knife, Angled
55-2825 2.85 x 3.5 mm Trapezoid Knife, Angled
55-2826 2.85 x 3.75 mm Trapezoid Knife, Angled
55-2924 3.0 x 3.2 mm Trapezoid Knife, Angled

Vitrectomy Knives

51-1901 19 Gauge Vitrectomy Knife, Straight
51-2001 20 Gauge Vitrectomy Knife, Straight
51-2061 20 Gauge Vitrectomy Knife, Angled
51-2301 23 Gauge Vitrectomy Knife, Straight
51-2361 23 Gauge Vitrectomy Knife, Angled
51-2501 25 Gauge Vitrectomy Knife, Straight
51-2531 25 Gauge Vitrectomy Knife, Angled

UniqueEdge® Guarded Knives

Clear Corneal Knives

52-2635-G 2.65 mm SC Clear Corneal Knife, Angled, Guarded
52-2763-G 2.75mm Clear Corneal Knife, Angled, Guarded

UniBevel Clear Corneal Knives

52-3042-G 3.0 mm UniBevel Clear Corneal Knife, Angled, Guarded
52-3242-G 3.2 mm UniBevel Clear Corneal Knife, Angled, Guarded

Crescent Knives

54-1010-G 2.0 mm Crescent Knife, Angled, Guarded
54-1012-G 2.2 mm Crescent Knife, Angled, Guarded

MVR Sideport Knives

58-2010-G 1.0 mm MVR Sideport Knife, Angled, Guarded





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58-2011-G 1.1 mm MVR Sideport Knife, Angled, Guarded
58-2012-G 1.2 mm (20G) MVR Sideport Knife, Angled, Guarded
58-2312-G 1.2 mm (20G) MVR Sideport Knife, Straight, Guarded
Slit Knives
52-2063-G 2.0 mm MicroPhaco Slit Knife, Angled, Guarded
52-2261-G 2.2 mm MicroPhaco Slit Knife, Angled, Guarded
52-2461-G 2.4 mm Slit Knife, Angled, Guarded
52-2561-G 2.5 mm Slit Knife, Angled, Guarded
52-2661-G 2.65 mm Slit Knife, Angled, Guarded
52-2761-G 2.75 mm Slit Knife, Angled, Guarded
52-2808-G 2.8 mm Slit Knife, Angled, Guarded
52-2861-G 2.85 mm Slit Knife, Angled, Guarded
52-2961-G 3.0 mm Slit Knife, Angled, Guarded
52-3261-G 3.2 mm Slit Knife, Angled, Guarded
Double Bevel Slit Knives
52-2263-G 2.2 mm CMP Knife, Angled, Double Bevel, Guarded
AK Slit Knives
52-1252-G 1.2 mm Double Bevel AK Slit Knife, Angled, Guarded
52-2552-G 2.5 mm Double Bevel AK Slit Knife, Angled, Guarded
52-2652-G 2.65 mm Double Bevel AK Slit Knife, Angled, Guarded
52-2850-G 2.85 mm AK Slit Knife, Angled, Guarded
UniBevel Slit Knives
52-1040-G 1.0 mm UniBevel Slit Knife, Angled, Guarded
52-1840-G 1.8 mm UniBevel Slit Knife, Angled, Guarded
52-2040-G 2.0 mm UniBevel Slit Knife, Angled, Guarded
52-2240-G 2.2 mm UniBevel Slit Knife, Angled, Guarded
52-2440-G 2.4mm UniBevel Slit Knife, Angled, Guarded
52-2540-G 2.5mm UniBevel Slit Knife, Angled, Guarded
52-2640-G 2.65mm UniBevel Slit Knife, Angled, Guarded
52-2740-G 2.75mm UniBevel Slit Knife, Angled, Guarded
52-2848-G 2.8 mm UniBevel Slit Knife, Angled, Guarded
52-3040-G 3.0 mm UniBevel Slit Knife, Angled, Guarded
52-3240-G 3.2 mm UniBevel Slit Knife, Angled, Guarded
Stab Knives
52-1501-G 15 Deg. Stab Knife, Guarded
52-2201-G 22.5 Deg. Stab Knife, Guarded
52-3001-G 30 Deg. Stab Knife, Guarded
52-4501-G 45 Deg. Stab Knife, Guarded
UniqueEdge® Blades & Threaded Tips
58-7110 Upward Cut, Adult Myringotomy Blade
58-7120 Spear Tip, Narrow Shaft, Myringotomy Blade
58-7121 Lance Tip, Narrow Shaft, Myringotomy Blade
52-2902F 3.0 mm Slit Blade, Straight, Flatstock
58-5700 #57 Scleral Blade
58-6400 #64 Blade
58-6600 #66 Lamellar Blade
58-6700 #67 Blade
58-6900 #69 Blade
52-1502 15 Deg. Stab Blade & Threaded Tip
52-1532 15 Deg. 3 mm Restricted Depth Stab Blade & Threaded Tip
52-1552 15 Deg. 5 mm Restricted Depth Stab Blade & Threaded Tip
52-2202 22.5 Deg. Stab Blade & Threaded Tip
52-2662 2.65 mm Slit Blade & Threaded Tip, Angled
52-2762 2.75 mm Slit Blade & Threaded Tip, Angled
52-2862 2.85 mm Slit Blade & Threaded Tip, Angled
52-2962 3.0 mm Slit Blade & Threaded Tip, Angled
52-3002 30 Deg. Stab Blade & Threaded Tip
52-3262 3.2 mm Slit Blade & Threaded Tip, Angled





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54-5000 2.0mm Crescent Blade & Threaded Tip, Straight
54-5062 2.0mm Crescent Blade & Threaded Tip, Angled
58-5702 #57 Blade & Threaded Tip
58-6602 6600 Lamellar Blade & Threaded Tip, Angled
58-6902 #69 Blade & Threaded Tip
UniqueEdge® Nonsterile Products (sold in bulk)
51-1901-NS 19 Gauge Vitrectomy Knife, Straight
51-2001-NS 20 Gauge Vitrectomy Knife, Straight
52-1501-NS 15 Deg. Stab Knife
52-1502-NS 15 Deg. Stab Blade & Threaded Tip
52-2261-NS 2.2 mm MicroPhaco Slit Knife, Angled
52-2461-NS 2.4 mm Slit Knife, Angled
52-2531-G-NS 2.5 mm Slit Knife, Angled, Double Bevel, Guarded
52-2531-NS 2.5 mm Slit Knife, Angled, Double Bevel
52-2661-NS 2.65 mm Slit Knife, Angled
52-2735-NS 2.75 mm SC Clear Corneal Knife, Angled
52-2740-NS 2.75 mm UniBevel Slit Knife, Angled
52-2761-NS 2.75 mm Slit Knife, Angled
52-2808-NS 2.8 mm Slit Knife, Angled
52-3261-NS 3.2 mm Slit Knife, Angled
52-4501-G-NS 45 Deg. Stab Knife, Guarded
52-4501-NS 45 Deg. Stab Knife
55-2022-NS 2.0 x 2.2 mm Trapezoid Knife, Angled
58-2010-NS 1.0 mm MVR Sideport Knife, Angled
58-2012-NS 1.2 mm (20G) MVR Sideport Knife, Angled

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

