



**Certificate No. 12922-9-2022**

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

(Three Pages)

**Name of Manufacturer/Distributor, Address**

Name of Manufacturer

Vortex Surgical  
4 Research Park Dr Suite 124  
Saint Charles, MO USA 63304

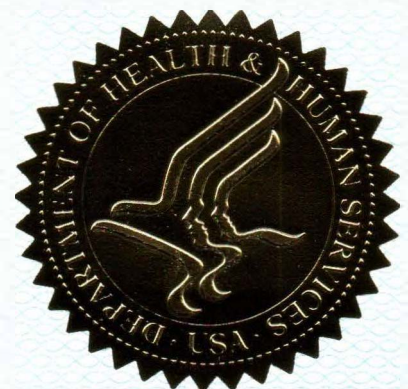
The product(s) described above (and the manufacturing/distribution site(s) which produces/distributes it) is subject to the jurisdiction of the FDA under the Federal Food, Drug, and Cosmetic Act.

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.

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 September 06, 2022 to September 05, 2024.**



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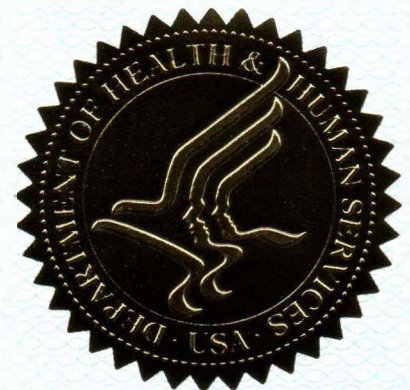
**Certificate to Foreign Government - Name of Product(s) Attachment Page 1 of 3**

**Name of Manufacturer**

Vortex Surgical  
4 Research Park Dr  
Suite 124  
Saint Charles, MO  
USA 63304

**Name of Product(s)**

VS0125.25 - 25ga Illuminated Curved Laser Probe - Manual Ophthalmic Surgical Device  
VS0125.23 - 23ga Illuminated Curved Laser Probe - Manual Ophthalmic Surgical Device  
VS02251 - Nano SubRet Gateway Device - Single - Manual Ophthalmic Surgical Device  
VS0203.27 - 27ga Dual Port Cannula - Manual Ophthalmic Surgical Device  
VS0201.27 - 27ga Blunt Tip Cannula - Manual Ophthalmic Surgical Device  
VS0200.25B - 25ga Soft Tip Cannula - Bulk - Manual Ophthalmic Surgical Device  
VS0200.23B - 23ga Soft Tip Cannula - Bulk - Manual Ophthalmic Surgical Device  
VS0240.30 - 30ga PC Maintainer - Manual Ophthalmic Surgical Device  
VS0745.25 - 25ga Asymmetrical Forceps - Manual Ophthalmic Surgical Device  
VS0745.23 - 23ga Asymmetrical Forceps - Manual Ophthalmic Surgical Device  
VS0744.25-35 - 25ga Myopic ILM Forceps - Manual Ophthalmic Surgical Device  
VS0744.23-35 - 23ga Myopic ILM Forceps - Manual Ophthalmic Surgical Device  
VS0742.25-35 - 25ga Myopic Tewari (T2) Forceps - Manual Ophthalmic Surgical Device  
VS0742.23-35 - 23ga Myopic Tewari (T2) Forceps - Manual Ophthalmic Surgical Device  
VS0740.27 - 27ga Adaptive Forceps - Manual Ophthalmic Surgical Device  
VS0713.27 - 27ga Pro-Grip Forceps - Manual Ophthalmic Surgical Device  
VS0744.27 - 27ga ILM Forceps - Manual Ophthalmic Surgical Device  
VS0801D - TID Pharos DORC  
VS0801B - TID Pharos Bausch and Lomb  
VS0275.27 - 27ga Retractable Backflush  
VS0275.25 - 25ga Retractable Backflush  
VS0275.23 - 23ga Retractable Backflush  
VS0270.27 - 27ga Backflush  
VS0270.25 - 25ga Backflush  
VS0270.23 - 23ga Backflush  
VS0810A - TID Pharos Alcon Constellation  
VS0800 - Todorich Illuminated Depressor  
VS0225C - Curved NANO Subret Device  
VS0225 - NANO Subret Device  
VS0250.25 - 25ga IDD  
VS0290C - Curved External Drainage and Depression  
VS0290 - External Drainage and Depression  
VS0140.27 - 27ga MAXReach Laser Probe  
VS0201.25 - 25ga Blunt Cannula  
VS0201.23 - 23ga Blunt Cannula  
VS0200.23 - 23ga Soft Tip Cannula - Manual Ophthalmic Surgical Device  
VS0200.25 - 25ga Soft Tip Cannula - Manual Ophthalmic Surgical Device  
VS0200.27 - 27ga Soft Tip Cannula - Manual Ophthalmic Surgical Device  
VS0210.23 - 23ga Slotted Soft Tip Cannula - Manual Ophthalmic Surgical Device  
VS0210.25 - 25ga Slotted Sift Tip Cannula - Manual Ophthalmic Surgical Device  
VS0220.25 - 25ga Subretinal Injection Cannula - Manual Ophthalmic Surgical Device  
VS0280.23 - 23ga Versatile Soft Tip Cannula - Manual Ophthalmic Surgical Device  
VS0280.25 - 25ga Versatile Soft Tip Cannula - Manual Ophthalmic Surgical Device  
VS0300.23 - 23ga Edge Advantage ILM Membrane Elevator - Manual Ophthalmic Surgical Device  
VS0300.25 - 25ga Edge Advantage ILM Membrane Elevator - Manual Ophthalmic Surgical Device  
VS0350.23 - 23ga Retractable Edge Advantage ILM Membrane Elevator - Manual Ophthalmic Surgical Device  
VS0350.25 - 25ga Retractable Edge Advantage ILM Membrane Elevator - Manual Ophthalmic Surgical Device  
VS0380.23 - 23ga Contour ILM Elevator - Manual Ophthalmic Surgical Device  
VS0380.25 - 25ga Contour ILM Elevator - Manual Ophthalmic Surgical Device  
VS0380.27 - 27ga Contour ILM Elevator - Manual Ophthalmic Surgical Device



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VS0500 - Injection Kit - Speculum, Marker  
VS0510 - Injection Kit - Basic  
VS0520 - Injection Kit - Basic plus Drape  
VS0640.23-FES - Adaptive Kit - 23ga (Flat Lens, Retractable Edge Advantage, Soft Tip)  
VS0640.25-FES - Adaptive Kit - 25ga (Flat Lens, Retractable Edge Advantage, Soft Tip)  
VS0640.23-FEX - Adaptive Kit - 23ga (Flat Lens, Retractable Edge Advantage)  
VS0640.25-FEX - Adaptive Kit - 25ga (Flat Lens, Retractable Edge Advantage)  
VS0640.23-FXS - Adaptive Kit - 23ga (Flat Lens, Soft Tip)  
VS0640.25-FXS - Adaptive Kit - 25ga (Flat Lens, Soft Tip)  
VS0640.23-FXX - \*Adaptive Kit - 23ga (Flat Lens)  
VS0640.25-FXX - \*Adaptive Kit - 25ga (Flat Lens)  
VS0640.23-XES - \*Adaptive Kit - 23ga (Retractable Edge Advantage, Soft Tip)  
VS0640.25-XES - \*Adaptive Kit - 25ga (Retractable Edge Advantage, Soft Tip)  
VS0640.23-XEX - \*Adaptive Kit - 23ga (Retractable Edge Advantage)  
VS0640.25-XEX - \*Adaptive Kit - 25ga (Retractable Edge Advantage)  
VS0640.23-XXS - \*Adaptive Kit - 23ga (Soft Tip)  
VS0640.25-XXS - \*Adaptive Kit - 25ga (Soft Tip)  
VS0642.23-FES - \*Tewari Kit - 23ga (Flat Lens, Retractable Edge Advantage, Soft Tip)  
VS0642.25-FES - \*Tewari Kit - 25ga (Flat Lens, Retractable Edge Advantage, Soft Tip)  
VS0642.23-FEX - \*Tewari Kit - 23ga (Flat Lens, Retractable Edge Advantage)  
VS0642.25-FEX - \*Tewari Kit - 25ga (Flat Lens, Retractable Edge Advantage)  
VS0642.23-FXS - Tewari Kit - 23ga (Flat Lens, Soft Tip)  
VS0642.25-FXS - Tewari Kit - 25ga (Flat Lens, Soft Tip)  
VS0642.23-FXX - \*Tewari Kit - 23ga (Flat Lens)  
VS0642.25-FXX - \*Tewari Kit - 25ga (Flat Lens)  
VS0642.23-XES - \*Tewari Kit - 23ga (Retractable Edge Advantage, Soft Tip)  
VS0642.25-XES - \*Tewari Kit - 25ga (Retractable Edge Advantage, Soft Tip)  
VS0642.23-XEX - \*Tewari Kit - 23ga (Retractable Edge Advantage)  
VS0642.25-XEX - \*Tewari Kit - 25ga (Retractable Edge Advantage)  
VS0642.23-XXS - \*Tewari Kit - 23ga (Soft Tip)  
VS0642.25-XXS - \*Tewari Kit - 23ga (Soft Tip)  
VS0644.23-FES - \*ILM Kit - 23ga (Flat Lens, Retractable Edge Advantage, Soft Tip)  
VS0644.25-FES - \*ILM Kit - 25ga (Flat Lens, Retractable Edge Advantage, Soft Tip)  
VS0644.23-FEX - \*ILM Kit - 23ga (Flat Lens, Retractable Edge Advantage)  
VS0644.25-FEX - \*ILM Kit - 25ga (Flat Lens, Retractable Edge Advantage)  
VS0644.23-FXS - ILM Kit - 23ga (Flat Lens, Soft Tip)  
VS0644.25-FXS - ILM Kit - 25ga (Flat Lens, Soft Tip)  
VS0644.23-FXX - \*ILM Kit - 23ga (Flat Lens) - Manual Ophthalmic Surgical Kit  
VS0644.25-FXX - \*ILM Kit - 25ga (Flat Lens) - Manual Ophthalmic Surgical Kit  
VS0644.23-XES - \*ILM Kit - 23ga (Retractable Edge Advantage, Soft Tip) - Manual Ophthalmic Surgical Kit  
VS0644.25-XES - \*ILM Kit - 25ga (Retractable Edge Advantage, Soft Tip) - Manual Ophthalmic Surgical Kit  
VS0644.23-XEX - \*ILM Kit - 23ga (Retractable Edge Advantage) - Manual Ophthalmic Surgical Kit  
VS0644.25-XEX - \*ILM Kit - 25ga (Retractable Edge Advantage) - Manual Ophthalmic Surgical Kit  
VS0644.23-XXS - \*ILM Kit - 23ga (Soft Tip) - Manual Ophthalmic Surgical Kit  
VS0644.25-XXS - \*ILM Kit - 25ga (Soft Tip) - Manual Ophthalmic Surgical Kit  
VS0713.23 - 23ga Pro-Grip Forceps - Manual Ophthalmic Surgical Device  
VS0713.25 - 25ga Pro-Grip Forceps - Manual Ophthalmic Surgical Device  
VS0740.23 - 23ga Adaptive Forceps - Manual Ophthalmic Surgical Device  
VS0740.25 - 25ga Adaptive Forceps - Manual Ophthalmic Surgical Device  
VS0742.23 - 23ga Tewari (T2) Forceps - Manual Ophthalmic Surgical Device  
VS0742.25 - 25ga Tewari (T2) Forceps - Manual Ophthalmic Surgical Device  
VS0743.23 - 23ga End Grip Forceps - Manual Ophthalmic Surgical Device  
VS0743.25 - 25ga End Grip Forceps - Manual Ophthalmic Surgical Device  
VS0744.23 - 23ga ILM Forceps - Manual Ophthalmic Surgical Device  
VS0744.25 - 25ga ILM Forceps - Manual Ophthalmic Surgical Device  
VS0110.23 - 23ga Straight Laser Probe - Manual Ophthalmic Surgical Device  
VS0110.25 - 25ga Straight Laser Probe - Manual Ophthalmic Surgical Device  
VS0110.27 - 27ga Straight Laser Probe - Manual Ophthalmic Surgical Device



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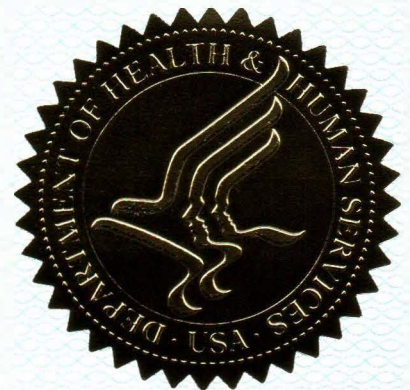


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VS0120.23 - 23ga Curved Laser Probe - Manual Ophthalmic Surgical Device  
VS0120.25 - 25ga Curved Laser Probe - Manual Ophthalmic Surgical Device  
VS0120.27 - 27ga Curved Laser Probe - Manual Ophthalmic Surgical Device  
VS0130.23 - 23ga Flexible Tip Laser Probe - Manual Ophthalmic Surgical Device  
VS0130.25 - 25ga Flexible Tapered Laser Probe - Manual Ophthalmic Surgical Device  
VS0130.27 - 27ga Flexible Tip Laser Probe - Manual Ophthalmic Surgical Device  
VS0140.23 - 23ga Max Reach Laser Probe - Manual Ophthalmic Surgical Device  
VS0140.25 - 25ga Max Reach Laser Probe - Manual Ophthalmic Surgical Device

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



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