



Certificate No. 11509-7-2024-3

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 August 22, 2024 to August 21, 2026.



To verify the authenticity of the information on this certificate, you may scan the QR code or visit www.access.fda.gov/fecv/CDRH.



**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

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

Name of Corporate Headquarters

CUSTOM ASSEMBLIES, INC.

330 E. Main St.

Pine Level, NC

USA 27568

Name of Manufacturer

CUSTOM ASSEMBLIES, INC.

330 EAST MAIN STREET

PINE LEVEL, NC

USA 27568

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





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

Name of Corporate Headquarters

CUSTOM ASSEMBLIES, INC.
330 E. Main St.
Pine Level, NC
USA 27568

Name of Manufacturer

CUSTOM ASSEMBLIES, INC.
330 EAST MAIN STREET
PINE LEVEL, NC
USA 27568

Name of Product(s)

SET, ADMINISTRATION, INTRAVASCULAR
CMS-1105 TUMESCENT HAND PUMP SET (STERILE)
CMS-1113 CONTRAST TRANSFER SET W/SWABLE CONNECTOR (STERILE)
CMS-1211 INFILTRATION TUBING SET WITH DRIP CHAMBER (STERILE)
CMS-1212 SINGLE SPIKE INFILTRATION TUBING SET (STERILE)
CMS-1216 DOUBLE SPIKE INFILTRATION SET (STERILE)
CMS-150 60" COILED INJECTION LINE (STERILE)
CMS-151 72" COILED INJECTION LINE (STERILE)
CMS-1622 96" COILED Y CONNECTOR PACK (STERILE)
TUBING, NONINVASIVE
CMS-1217 9' ASPIRATION TUBING (STERILE)
CMS-1218 12' ASPIRATION TUBING (STERILE)
CMS-1228 9' BUBBLE TUBING (STERILE)
CMS-1238 12' BUBBLE TUBING (STERILE)
GENERAL SURGERY TRAY
CMS-200-2 BIOPSY PROCEDURE KIT (STERILE)
CMS-231-2 MYELOGRAM PROCEDURE KIT (STERILE)
CMS-300 BIOPSY PROCEDURE KIT (STERILE)
CMS-2012-R3 DRAINAGE PROCEDURE KIT (STERILE)
CMS-4439-R5 BIOPSY PROCEDURE KIT (STERILE)
CMS-9110-A BREAST BIOPSY TRAY (STERILE)
CMS-5650-R2 EPIDURAL INJECTION PROCEDURE KIT (STERILE)
CMS-1637 NEEDLE HOLDER (STERILE)
TABLE AND TABLE ATTACHMENTS, OPERATING-ROOM
CMS-900V UROLOGICAL DRAINBAG (STERILE)
CMS-904P UROLOGICAL DRAINBAG (STERILE)
CMS-904V UROLOGICAL DRAINBAG (STERILE)
CMS-905P UROLOGICAL DRAINBAG (STERILE)
CMS-905P-6 UROLOGICAL DRAINBAG W/6MM ADAPTOR (STERILE)
CMS-905V UROLOGIC DRAINBAG (STERILE)
CMS-905V-6 UROLOGICAL DRAINBAG W/6MM ADAPTOR (STERILE)
CMS-905V-8 UROLOGICAL DRAINBAG W/8MM ADAPTOR (STERILE)
CMS-907 COMBO PACK WITH 1 EACH CMS-954P & CMS-655 (NON-STERILE)
CMS-909-8 UNIVERSAL DRAINBAG W/8MM ADAPTER (STERILE)
CMS-910V COMBO PACK (NON-STERILE)
CMS-912V UROLOGICAL COMBO PACK (NON-STERILE)
CMS-919VT UROLOGICAL COMBO PACK (NON-STERILE)
CMS-942V UROLOGICAL COMBO PACK (NON-STERILE)
CMS-950P-10 UROLOGICAL DRAINBAG W/ 10MM ADAPTOR PLUG (NON-STERILE)
CMS-950P-6 UROLOGICAL DRAINBAG W/ 6MM ADAPTOR PLUG (NON-STERILE)
CMS-950P-8 UROLOGICAL DRAINBAG W/ 8MM ADAPTOR PLUG (NON-STERILE)
CMS-950PXL UROLOGICAL DRAINBAG W/ XL HOSE (NON-STERILE)
CMS-950V-8 UROLOGICAL DRAINBAG W/ 8MM ADAPTOR PLUG (NON-STERILE)
CMS-950VXL UROLOGICAL DRAINBAG W/ XL HOSE (NON-STERILE)
CMS-951V-6 UROLOGICAL DRAINBAG W/ 6MM ADAPTOR (NON-STERILE)





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CMS-954P-10 UROLOGIC DRAINBAG W/ 10MM ADAPTOR (NON-STERILE)
CMS-954P-6 UROLOGIC DRAINBAG W/ 6MM ADAPTOR (NON-STERILE)
CMS-954P-8 UROLOGIC DRAINBAG W/ 8MM ADAPTOR (NON-STERILE)
CMS-954V-6 UROLOGIC DRAINBAG W/ 6MM ADAPTOR (NON-STERILE)
CMS-954V-8 UROLOGIC DRAINBAG W/ 8MM ADAPTOR (NON-STERILE)
CMS-955P-10 UROLOGIC DRAINBAG W/ 10MM ADAPTOR (NON-STERILE)
CMS-955P-6 UROLOGIC DRAINBAG W/ 6MM ADAPTOR (NON-STERILE)
CMS-955P-8 UROLOGIC DRAINBAG W/ 8MM ADAPTOR (NON-STERILE)
CMS-955V-6 UROLOGIC DRAINBAG W/ 6MM ADAPTOR (NON-STERILE)
CMS-955V-8 UROLOGIC DRAINBAG W/ 8MM ADAPTOR (NON-STERILE)
CMS-969P UROLOGIC DRAINBAG (STERILE)
CMS-987 UNIVERSAL UROLOGICAL COMBO PACK (NON-STERILE)
CMS-999-10 UNIVERSAL DRAINBAG W/ 10MM ADAPTER (NON-STERILE)
CMS-999-6 UNIVERSAL DRAINBAG W/ 6MM ADAPTER (NON-STERILE)
CMS-999-8 UNIVERSAL DRAINBAG W/ 8MM ADAPTER (NON-STERILE)
CMS-999XL UNIVERSAL DRAINBAG WITH XL HOSE (NON-STERILE)
CMS-950P UROLOGICAL DRAINBAG (NON-STERILE)
CMS-950V UROLOGICAL DRAINBAG (NON-STERILE)
CMS-951V UROLOGICAL DRAINBAG (NON-STERILE)
CMS-954P UROLOGICAL DRAINBAG (NON-STERILE)
CMS-954V UROLOGICAL DRAINBAG (NON-STERILE)
CMS-955P UROLOGICAL DRAINBAG (STERILE)
CMS-955V UROLOGICAL DRAINBAG (STERILE)
CMS-999 UNIVERSAL UROLOGIC DRAINBAG (NON-STERILE)
CMS-909 UNIVERSAL UROLOGIC DRAINBAG (STERILE)

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

