REGISTRATION NO.: 9710483
FOR: 2005

OWNER / OPERATOR NO.: 9045867

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

ANNUAL REGISTRATION OF DEVICE ESTABLISHMENT

NOTE: This form is authorized by Section 510 of the Food, Drug, and Cosmetic Act (21 U.S.C. 360). Failure to report this information is a violation of Section 301(p) of the Act (21 U.S.C. 331(p)). Persons who violate this provision may, if convicted, be subject to fine or imprisonment or both. The submission of any report that is false or misleading in any material respect is a violation of Section 301(q)(2) (21 U.S.C. 331(q)(2)) and may be a violation of 18 U.S.C. 1001.

REGISTERED ESTABLISHMENT

KHRUNICHEV STATE RESEARCH & PRODUCTION SPACE
NOVOZAVODSKAYA, 18
MOSCOW
121309 RUSSIA

OWNER / OPERATOR

KHRUNICHEV STATE RESEARCH & PRODUCTION SP
NOVOZAVODSKAYA, 18
MOSCOW
121309 RUSSIA

OFFICIAL CORRESPONDENT

MR. GLEB M MITINSKI
KHRUNICHEV STATE RESEARCH & PRODUCTION SPACE CENTR
NOVOZAVODSKAYA, 18
MOSCOW
121309 RUSSIA

ESTABLISHMENT TYPE MANUFACTURER

Detach Part 1 and Keep as Proof of Registration.
Complete and Return Part 2.
Detach and Refer to Part 3 for Specific Instructions.

ESTABLISHMENT TYPE DEFINITIONS

ESTABLISHMENT TYPE - Space is provided for each designated code for establishment type. Select from the following descriptions the appropriate code or codes that reflect the device activity of the establishment. Check the appropriate designation(s) in the boxes provided.

E *CONTRACT MANUFACTURER - Manufactures a finished device to another establishment's specifications. The manufacturing establishment does not commercially distribute the device under its own name.

M MANUFACTURER - Makes by chemical, physical, biological, or other procedures, any article that meets the definition of "device" in section 201(h) of the Federal Food, Drug and Cosmetic (FD&C) Act.

R REPACKAGER AND/OR RELABELER - Repackager: Packages finished devices from bulk or repackages devices made for the establishment by a manufacturer into different containers (excluding shipping containers).
Relabeler: Changes the content of the labeling from that supplied from the original manufacturer for distribution under the establishment's own name. (This does not include establishments that do not change the original labeling but merely add their own name.)

S SPECIFICATION DEVELOPER - Develops specifications for a device that is distributed under the establishment's own name but performs no manufacturing.

T *CONTRACT STERILIZER - Provides a sterilization service for another establishment's devices.

ID INITIAL DISTRIBUTOR/IMPORTER - Takes first title to imported devices.

X REMANUFACTURER - Person who processes, conditions, renovates, repackages, restores, or performs any other act to a finished device that significantly changes the device's performance specifications, safety specifications, or intended use.

MB REPROCESSOR - Person who performs remanufacturing operations on a single use device.

FE FOREIGN EXPORTER - Person who exports or offers for export to the United States, a device manufactured or processed by another person in a foreign country.

*NOTE: A September 1, 1993 Federal Register notice erroneously exempted contract manufacturers and contract sterilizers from registration. That exemption will be revoked.