



**Certificate No. 12794-7-2021**

**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**

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.

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 04, 2021 to August 03, 2023.**





U.S. Food & Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993  
[www.fda.gov](http://www.fda.gov)

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

**Name of Manufacturer/Distributor**

DIAMOND DIAGNOSTICS Inc  
333 Fiske St  
Holliston, MA  
USA 01746

Diamond Diagnostics Inc. Hungary Branch Office  
6 Oradna Street  
Budapest, Budapest  
HUNGARY 1044

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





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**Name of Manufacturer/Distributor**

DIAMOND DIAGNOSTICS Inc  
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Holliston, MA  
USA 01746

Diamond Diagnostics Inc. Hungary Branch Office  
6 Oradna Street  
Budapest, Budapest  
HUNGARY 1044

**Name of Product(s)**

Descriptive Title: Clinical Chemistry Test Systems

0-DD-CARELYTE DIAMOND CARELYTE ELECTROLYTE ANALYZER  
0-DD-CARELYTEPLUS DIAMOND CARELYTE ELECTROLYTE ANALYZER  
0-DD-PROLYTE DIAMOND PROLYTE ELECTROLYTE ANALYZER  
0-DD-SMARTLYTE DIAMOND SMARTLYTE ELECTROLYTE ANALYZER  
0-DD-SMARTLYTEPLUS DIAMOND SMARTLYTE PLUS ISE ANALYZER  
0-DD-UNITY DIAMOND ISE MODULE  
AB-08C9435D WASH PROBE ASSEMBLY  
AB-08C9487D TEMPERATURE SENSOR  
AB-77665002D MAINTENANCE KIT  
AB-8921153401/1 COMPRESSOR SERVICE KIT  
AB-9216102D WASTE SENSOR  
AV-BP0095D REFERENCE SOLUTION  
AV-BP0344D URINE DILUENT  
AV-BP0359D K+ ELECTRODE  
AV-BP0360D CA++ ELECTRODE  
AV-BP0380D ELECTRODE CONDITIONING SOLUTION  
AV-BP0413D NA+ ELECTRODE  
AV-BP0442D STANDARD B  
AV-BP0521D DEPROTEINIZER SOLUTION  
AV-BP0570D CL- ELECTRODE  
AV-BP0962D LI+ ELECTRODE  
AV-BP1025D ISE CLEANING SOLUTION  
AV-BP5006D SAMPLE PROBE  
AV-BP5012D PINCH VALVE TUBING KIT  
AV-BP5014D SHUTDOWN KIT  
AV-BP5016D FLUID PACK  
AV-BP5019D REFERENCE ELECTRODE HOUSING  
AV-BP5025D PRINTER PAPER  
AV-BP5026D REFERENCE ELECTRODE  
AV-BP5027D PERISTALTIC PUMP TUBING  
AV-BP5032D FLUID PACK  
AV-BP5036D SAMPLE SENSOR  
AV-BP5186D FLUID PACK  
AV-BP5193D PINCH VALVE TUBING KIT  
AV-BP5194D STARTUP KIT  
AV-BP9043D FILLPORT ASSEMBLY  
AW-402377D SAMPLE PROBE  
AW-903393D NA+ ELECTRODE  
AW-903394D K+ ELECTRODE  
AW-906178D CL- ELECTRODE  
AW-906179D REFERENCE ELECTRODE HOUSING  
AW-906182D PUMP TUBING  
AW-SA1021D SYSTEM DILUENT  
AW-SA1029D CAL A SOLUTION  
BK-441930D CL- ELECTRODE





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- BK-443320D CO2 ALKALINE BUFFER
- BK-443335D WASH CONCENTRATE SOLUTION
- BK-443340D CREATININE REAGENT
- BK-443350D BUN REAGENT
- BK-443355D GLUCOSE REAGENT
- BK-445865D WASH 2 CONCENTRATE
- BK-465908D LEVEL 1 CALIBRATOR
- BK-465909D LEVEL 2 CALIBRATOR
- BK-465910D LEVEL 3 CALIBRATOR
- BK-465986D TOTAL PROTEIN REAGENT
- BK-467858D ALBUMIN REAGENT
- BK-467868D PHOSPHORUS REAGENT
- BK-467915D ISE BUFFER REAGENT
- BK-467935D ISE REFERENCE REAGENT
- BK-469499D GLUCOSE ELECTRODE
- BK-472481D CO2 ACID REAGENT
- BK-472482D BUN REAGENT
- BK-472500D GLUCOSE REAGENT
- BK-472515D CO2 ALKALINE BUFFER
- BK-472525D CREATININE REAGENT
- BK-476015D PROBE RINSE SOLUTION
- BK-A17647D CO2 ACID REAGENT
- BK-A17652D ISE BUFFER REAGENT
- BK-A17657D ISE REFERENCE REAGENT
- BK-A44148D COMPRESSOR SERVICE KIT
- BM-1131079D SYSTEM CLEANING SOLUTION
- BM-1135329D HITERGENT SOLUTION
- BM-1224310D CELL CLEAN
- BM-1489828D ISE COMPENSATOR
- BM-371037D NA+ ELECTRODE
- BM-371038D K+ ELECTRODE
- BM-372039D CL- ELECTRODE
- BM-373039D REFERENCE ELECTRODE
- BM-409079D HALOGEN LAMP
- BM-409149D HITERGENT SOLUTION
- BM-450041D KCL ELECTROLYTE SOLUTION
- BM-450042D ISE INTERNAL REFERENCE SOLUTION
- BM-450043D ISE DILUENT
- BM-620427D ISE HIGH STANDARD
- BM-620428D ISE LOW STANDARD
- BM-7070212D MIXING PADDLE
- BM-7140602D MIXING PADDLE
- BM-820637D ISE DILUENT
- BM-820638D ISE DILUENT
- BM-820639D KCL ELECTROLYTE SOLUTION
- BM-836246D ISE INTERNAL REFERENCE SOLUTION
- BT-6620940D ISE KIT
- BT-6620940SD ISE WASH SOLUTION
- BT-6620941D ISE REFERENCE SOLUTION
- BT-6620942D ISE BUFFER SOLUTION
- BT-6620943D ISE CALIBRATOR KIT, LOW
- BT-6620944D ISE CALIBRATOR KIT, HIGH
- BT-6620945D ENZYMATIC WASH KIT
- BT-6620947D ISE KIT
- CD-104226D WASH PACK
- CD-104227D BUFFER PACK
- CD-105610D DEPROTEINIZER SOLUTION
- CD-105673D PUMP TUBING KIT





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CD-473385D 7.3 SLOPE BUFFER  
CD-473386D 6.8 CAL BUFFER  
CD-473387D WASH/ZERO SOLUTION  
CD-473389D C1/C2 CLEANING SOLUTION  
CD-473496D BUFFER PACK  
CD-473497D WASH PACK  
CD-476266D SODIUM ELECTRODE  
CD-476267D PH ELECTRODE  
CD-476268D CALCIUM ELECTRODE  
CD-476270D POTASSIUM ELECTRODE  
CD-476273D REFERENCE ELECTRODE  
CD-476279D CHLORIDE ELECTRODE  
CD-478533D PH FILL SOLUTION  
CD-478535D NA-K-CA-CL FILL SOLUTION  
CD-478701D CONDITIONER SOLUTION  
CD-478822D REFERENCE FILL SOLUTION  
CD-570096D G/L CALIBRATOR  
CD-673252D PRINTER PAPER  
CD-673358D PUMP TUBING  
CD-673705D PUMP TUBING  
DA-D105D SALT BRIDGE SOLUTION  
DA-D828D CUVETTE CARTRIDGE  
DA-D829D PRINTER PAPER  
DA-S620D QUICKLYTE STANDARD A  
DA-S625D QUICKLYTE STANDARD B  
DA-S630D FLUSH SOLUTION  
DA-S635D QUICK IMT SAMPLE DILUENT  
DA-S640D QUICK IMT DILUENT CHECK  
DD-61010 CLEANING SOLUTION  
DD-61011 CONDITIONER  
DD-61011 CONDITIONER  
DD-61013 STANDARD B  
DD-61014 FLUID PACK WITH STANDARD B  
DD-61100 PUMP  
DD-61101 PERISTALTIC PUMP  
DD-61102 PINCH VALVE  
DD-61103 CPU BOARD  
DD-61104 ELECTRODE CABLE  
DD-61105 PUMP HEAD  
DD-61002 REFERENCE ELECTRODE HOUSING  
DD-62003 Na+ Electrode  
DD-62004 K+ Electrode  
DD-62005 Cl- Electrode  
DD-62006 SAMPLE SENSOR  
DD-92001 MISSION CONTROL LEVEL 1  
DD-92002 MISSION CONTROL LEVEL 2  
DD-92003 MISSION CONTROL LEVEL 3  
DD-92004 MISSION CONTROL LEVEL 4  
DD-92123 MISSION CONTROL LEVEL 1-2-3  
DD-92900 MISSION COMPLETE LINEARITY CONTROL, 5 LEVELS  
DD-93001 MISSION CLINICHECK LEVEL 1  
DD-93002 MISSION CLINICHECK LEVEL 2  
DD-93012 MISSION CLINICHECK LEVEL 1-2  
DD-93100 MISSION CLINICAL CALIBRATOR  
DD-96001 MISSION TRINITY B LEVEL 1  
DD-96002 MISSION TRINITY B LEVEL 2  
DD-96003 MISSION TRINITY B LEVEL 3  
DD-96123 MISSION TRINITY B LEVEL 1-2-3





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DD-97001 MISSION TRINITY R LEVEL 1  
DD-97002 MISSION TRINITY R LEVEL 2  
DD-97003 MISSION TRINITY R LEVEL 3  
DD-97123 MISSION TRINITY R LEVEL 1-2-3  
HM-XEA328ASD MAINTENANCE KIT  
HM-XEA486ORD ORING KIT  
IL-08007504D PRINTER PAPER  
IL-09756904D REFERENCE SOLUTION  
IL-18102002/1 SYRINGE SEAL, DILUTOR BLOCK  
IL-20002400D EMULSION WASH SOLUTION  
IL-2121D FLUID PACK  
IL-2121D+ FLUID PACK  
IL-2123D FLUID PACK  
ME-2095D MAINTENANCE KIT  
ME-2100D TUBING KIT, CALCIUM  
ME-2101D K+ ELECTRODE  
ME-2102D NA+ ELECTRODE  
ME-2103D REFERENCE ELECTRODE  
ME-2104D PUMP TUBING  
ME-2106D LI+ ELECTRODE  
ME-2107D SAMPLE PROBE  
ME-2108D SOLUTIONS VALVE  
ME-2111D URINE DILUENT  
ME-2113D CL- ELECTRODE  
ME-2118D DAILY RINSE KIT  
ME-2121D PACK  
ME-2123D PACK  
ME-2150D CA++ ELECTRODE  
ME-2257D SAMPLE DETECTOR  
ME-2258D MEMBRANE ASSEMBLY  
ME-2309D FLUSH SOLUTION  
ME-2323D PROBE WIPER SET  
ME-2492D INTERNAL FILLING SOLUTION  
ME-2541D PRINTER PAPER  
ME-2572D TROUBLESHOOTING SERVICE KIT  
ME-2577D URINE STANDARD  
ME-2578D RED TEST DYE  
ME-5410D STANDARD B, ISE MODULE  
ME-6370D SOLUTION, CALIBRANT A, MEDICA ISE MODULE  
MN-2121D PACK  
OY-AS0001D WASH SOLUTION  
OY-AUH1011D ISE BUFFER  
OY-AUH1012D ISE MID-STANDARD  
OY-AUH1013D ISE REFERENCE SOLUTION  
OY-AUH1014D ISE LOW STANDARD  
OY-AUH1015D ISE HIGH STANDARD  
OY-AUH1016D LOW/HIGH URINE STANDARD  
OY-AUH1017D INTERNAL REFERENCE SOLUTION  
OY-AUH1018D NA/K SELECTIVITY CHECK SOLUTION  
OY-AUH1019D CLEANING SOLUTION  
OY-MU9599D MIXING PADDLE, SPIRAL  
OY-MU9623D ROLLER PUMP TUBING  
OY-MU9888D HALOGEN LAMP  
OY-MU9934D SAMPLE PROBE  
OY-MU9958D REAGENT PROBE  
OY-OSR0001D WASH SOLUTION  
OY-ZM001600D SYRINGE, E  
OY-ZM001800D SYRINGE, G





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OY-ZM0635D HALOGEN LAMP  
OY-ZM2970D ISE PINCH VALVE TUBING  
RD-842194D PUMP TUBING  
RD-943791D 7.4 CAL SOLUTION  
RD-943792D 6.8 CAL SOLUTION  
RD-943793D RINSE SOLUTION  
RD-943794D SALT BRIDGE SOLUTION  
RD-943795D CLEANING SOLUTION  
RD-943827D PROTEIN REMOVER SOLUTION  
RD-943837D CAL 1 SOLUTION  
RD-943839D CAL 2 SOLUTION  
RD-943906D HYPOCHLORITE PROTEIN REMOVER  
RD-944071D RINSE SOLUTION  
RO-1029266D REAGENT PROBE  
RO-1029274D SAMPLE NEEDLE  
RO-1042282D REAGENT TIP CLEANER  
RO-1043864D SAMPLE NEEDLE  
RO-1046997D ISE STANDARD 1  
RO-1046998D ISE STANDARD 2  
RO-1046999D ISE REFERENCE SOLUTION  
RO-4522320D ISE INTERNAL STD  
RO-4522630D ISE DILUENT  
SM-B01417151D ISE BUFFER  
SM-B01417351D ISE REFERENCE SOLUTION  
SM-B01417452D ISE DETERGENT  
SM-B01417851D CUVETTE WASH SOLUTION  
SM-B01417951D CUVETTE CONDITIONER  
SM-B01418155D PROBE WASH, 1  
SM-B01418255D PROBE WASH, 2  
SM-B01418351D PROBE WASH, 3  
SM-B03417501D ISE SERUM STANDARD HIGH/LOW  
SM-B03417601D ISE URINE STANDARD HIGH/LOW  
SX-28144879D COMPRESSOR REBUILD KIT  
SX-44368656D COMPRESSOR REBUILD KIT  
TB-20270477D CALIBRATOR 1  
TB-20270478D CALIBRATOR 2  
TB-20270479D CLEANING SOLUTION  
TB-20270480D URINE CALIBRATOR 1-2  
TB-20270482D URINE DILUENT  
TB-30270905D CALIBRATOR 2  
TB-SP2208D ALKALINE WASHING SOLUTION

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

