

# Declaration of Conformity

<b>PRODUCT IDENTIFICATION</b>	
<b>Product Name</b>	<b>Model/Number</b>
Urine Analyzer	HTI CL-50 Plus HTI CL-500
Chemistry Analyzer	HTI BioChem SA HTI BioChem FC-120 HTI BioChem FC-200 HTI BioChem FC-360 Automated Chemistry Analyzer Type A HTI BioChem FC-360 Automated Chemistry Analyzer Type B HTI BioChem FC-360 Automated Chemistry Analyzer Type C HTI BioChem FC-360 Automated Chemistry Analyzer Type D
Electrolyte Analyzer	HTI E-Lyte Plus
Incubator Shaker	HTI ImmunoChem-2200
Microplate Washer	HTI ImmunoChem-2600 HTI ImmunoChem-2600 Plus
Hematology Analyzer	HTI MicroCC-20Plus HTI MicroCC-25Plus
Heat Block	HTI SA-18
Coagulation Analyzer	HTI TS4000
Chemistry Reagents	Acid Phosphatase Reagent Set Alanine Aminotransferase (ALT or SGPT) Reagent Set Albumin Reagent Set Alcohol Reagent Set Alcohol Standard Set Alkaline Phosphatase Reagent Set Ammonia Reagent Set Ammonia Standard Set Ammonia/Alcohol Control Set Amylase Reagent Set Aspartate aminotransferase (AST or SGOT) Reagent Set Bilirubin Direct (auto) Reagent Set Bilirubin Direct (semi-auto) Reagent Set Bilirubin Total (auto) Reagent Set Bilirubin Total (semi-auto) Reagent Set Calcium Arsenazo Reagent Set Calcium Reagent Set Chemistry Control Set Chemistry Multi-Calibrator Set Chloride Reagent Set Cholesterol Reagent Set Cleaning Solution CO2 Reagent Set

	<p>CO2 Standard Set C-reactive protein (CRP) HS Control Set C-reactive protein (CRP) HS Reagent Set C-reactive protein (CRP) HS Standard Set Creatine Kinase (CK) Reagent Set Creatine Kinase-MB Control Set Creatine Kinase-MB Reagent Set Creatinine Reagent Set Direct Total Iron-Binding Capacity (TIBC) Calibrator Set Direct Total Iron-Binding Capacity (TIBC) Reagent Set Fructosamine Calibrator Set Fructosamine Control Set Fructosamine Reagent Set Gamma-glutamyl transferase (GGT) Reagent Set Glucose Hexokinase Reagent Set Glucose Oxidase Reagent Set Glycohemoglobin Control Set Glycohemoglobin Reagent Set HDL/LDL Calibrator Set Hemoglobin A1c (HbA1c) Calibrator Set Hemoglobin A1c (HbA1c) Control Set Hemoglobin A1c (HbA1c) Reagent Set Hemoglobin Control Set Hemoglobin Reagent Set Hemoglobin Standard Set High-density lipoprotein (HDL) Reagent Set Homocysteine Calibrator Set Homocysteine Control Set Homocysteine Reagent Set Human Urine Control Set Iron (auto) Reagent Set Iron (semi-auto) Reagent Set Lactate dehydrogenase (LDH-L) Reagent Set Lactate Reagent Set Lactate Standard Set Lipase Reagent Set Lipid Control Set Low-density lipoprotein (LDL) Reagent Set Magnesium Reagent Set Microalbumin Calibrator Set Microalbumin Control Set Microalbumin Reagent Set Microprotein Reagent Set Microprotein Standard Set Phosphorus Reagent Set Potassium Reagent Set Precision Test Fluid Sodium (auto) Reagent Set Sodium (semi-auto) Reagent Set Sodium Calibrator Set Total Iron-Binding Capacity (TIBC) Reagent Set Total Protein Reagent Set Triglycerides Reagent Set Urea Nitrogen (BUN) Reagent Set Uric Acid Reagent Set Washing Solution</p>
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Hematology Reagents	HTI Diluent HTI Lytic Reagent HTI Detergent HTI Enzymatic Cleaner HTI Cleaning Solution HTI Sheath Focusing Solution HTI Enzymatic Cleaner Concentrate
Urine Reagent Strips	UrineRS H10 UrineRS A10 UrineRS E10 UrineRS H11 UrineRS H11-MA UrineRS H13 UrineRS H14 Calibration Urine Strips
Reagents for HTI Electrolyte Analyzer	Reagent Pack (Calibrant A, Calibrant B) Washing Solution (Activation) Washing Solution (Deproteinizer) Washing Solution (Cleaning ) Refill Solution for ISE Electrodes Refill Solution for Mg Electrode Refill Solution for Reference Electrode CO2 Calibration Solution 1 CO2 Calibration Solution 2 CO2 Acidic Washing Solution Urine Dilute Solution Linearity Control Material Electrode, Magnesium (Mg) Electrode, Lithium (Li) Electrode, Calcium (Ca) Electrode, Chloride (Cl) Electrode, Potassium (K) Electrode, Sodium (Na) Electrode, pH Electrode, Reference Dummy Electrode
Hemostasis Reagents	HT-Coag PT Reagent kit HT-Coag APTT Reagent kit HT-Coag Calcium Chloride Reagent kit HT-Coag Thrombin Time Reagent kit HT-Coag Fibrinogen Assay kit HT-Coag Thrombin Reagent kit (for Fib Assay) HT-Coag Control 1 Reagent kit HT-Coag Control 2 Reagent kit
ELISA Reagents	TSH ELISA kit

<b>MANUFACTURER</b>		
<b>Name of Company</b>	<b>Address</b>	<b>Representative</b>
High Technology, Inc.	20 Alice Agnew Dr., North Attleboro, MA 02763	Sasha Jassem +1 508-660-2221- phone +1 508-660-2224 – fax



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AUTHORIZED REPRESENTATIVE		
Name of Company	Address	Telephone/Email
Emergo Europe	Prinsessegracht 20 2514 AP The Hague The Netherlands	+31.70.345.8570 - phone europe@emergogroup.com

CONFORMITY ASSESSMENT		
Device Classification	Route to Compliance	Standards Applied
Class: Self-Certify	Annex III of IVDD 98/79/EC Council Directive	ISO 13485:2016

High Technology, Inc. declares that the above mentioned products meet the provision of the Council Directive 98/79/EC for *In Vitro* Diagnostic Medical Devices and Directive 98/79/EC as transposed in the national laws of the Member States.

**COMPANY REPRESENTATIVE:** Sasha Jassem

**TITLE:** Regulatory Affairs Manager

**SIGNATURE:**

**DATE:** 2022-03-15

