



BIOMEDICAL SYSTEMS

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## EC DECLARATION OF CONFORMITY

**Manufacturer's Name:**

ELITechGroup Inc.  
(d.b.a. Wescor, Inc.)

**Manufacturer's Address:**

370 West 1700 South  
Logan, Utah 84321 USA

**European Authorized Representative:**

**MT Promedt Consulting, GmbH**  
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**Declares, under sole responsibility, that the follow product/instrument,**

**Product Name:** Aerospray® Hematology Pro Slide Stainer  
**Model Number:** 7152  
**Type of Equipment:** AC line-powered, motorized slide stainer  
**GMDN Code:** 15599  
**IVDD Classification:** Other/General...not list A or B or Self-Test

**Conforms to the requirements of RoHS 2 Directive, (2011/65/EU), the applicable section of the European Union Council Directive for InVitro Medical Devices, IVDD 98/79/EC, and the associated Essential Requirements under Annex I. The following standards have been applied:**

**Electrical Safety**

CAN/CSA-C22.2 No. 61010-1:2012  
CAN/CSA-C22.2 No. 61010-2-020:2009  
CAN/CSA-C22.2 No. 61010-2-081: 2004/R:2009  
CAN/CSA-C22.2 No. 61010-2-101: 2004/R:2009  
EN 61010-1:2010, EN 61010-1:2001  
EN 61010-2-101:2002  
EN 61010-2-081+A1:2003  
EN 61010-2-020:2006  
UL 61010-1:2004+R:2005-07+R:2008-10

IEC 61010-1:2010, IEC 61010-1:2001  
IEC 61010-2-020:2006  
IEC 61010-2-081:2001+A1:2003  
IEC 61010-2-101:2002  
UL 61010-2-020:2002  
UL 61010-1:2012

**Electromagnetic Immunity and Electromagnetic Interference**

EN 61326-1: 2006 (IEC 61326-1: 2005) (Inclusive-IEC 61326-2-6:2005)  
EN 61000-3-2:2006+A1:2009,+A2:2009  
(IEC 61300-3-2:2005)+A1:2008+A2:2009  
EN 61000-3-3:2008 (IEC61000-3-3:2008)

**Additionally, the accessories and supplies listed hereafter conform to the requirements in the applicable section of the European Union Council Directive for InVitro Medical Devices, IVDD 98/79/EC, and the associated Essential Requirements under Annex I.**

**Accessories and Supplies:**

AC-038	Space-Saver Container with Cap, 5 L, Aerospray
AC-039	Spigot for AC-038 container, Aerospray
AC-041	Aerospray Drain Tube, 1.8 m
AC-043-05	Reagent bottle with cap, 500 mL, 5/PK, Aerospray
AC-043-160	Reagent bottle with cap, 500 mL, 160/PK, Aerospray
AC-057	30-slide vented carousel for Aerospray
AC-059	Aerospray Nozzle Orifice Cleaning Wire, 3 m
AC-069	Pump primer for Aerospray
AC-072	5L reagent bottle assembly w/barb fitting Aerospray
AC-184	Aerospray Nozzle Maintenance Kit
AC-110	Safety Shield for Aerospray/Cytopro
AC-160	Cytopro Rotor
AC-170	Waste container for Aerospray
AC-181	1D Barcode Reader with Stand
AC-182	Waste Container with level detection
AC-183	5L reagent bottle assembly w/level detection
AC-188	12 – Slide Carousel Aerospray Stainers
AC-189	30 – Slide Carousel Aerospray Stainers
RP-308	Nozzle/o-ring assy, SS, for Aerospray
SS-029	Aerospray Nozzle Cleaning Solution, 355mL
SS-029C	Aerospray Nozzle Cleaning Solution, 250 mL Concentrate
SS-029C-EU	Aerospray Nozzle Cleaning Solution, 250 mL Concentrate
SS-029CG	Nozzle Cleaning Solution, 1.89 liter Concentrate
SS-029CG-EU	Nozzle Cleaning Solution, 2.5 liter Concentrate
SS-048	Hematology Reagent D Aerofix Fixative, 500 mL
SS-048-EU	Hematology Reagent D Aerofix Fixative, 500 mL
SS-071A	Hematology Reagent A Buffer (pH 6.8), 1 gallon
SS-071B	Hematology Reagent B Thiazin, 500 mL
SS-071B-EU	Hematology Reagent B: Thiazin, 500 mL
SS-071C	Hematology Reagent C Eosin, 500 mL
SS-071C-EU	Hematology Reagent C: Eosin, 500 mL
SS-072A	Hematology Reagent A Buffer (pH 7.2), 1 gallon
SS-072A-EU	Hematology Reagent A Buffer (pH 7.2), 500 mL
SS-148	Hematology Aerofix Additive for MeOH, 135mL
SS-148-EU	Hematology Aerofix Additive for MeOH, 135mL
SS-171A	Hematology Reagent A Buffer (pH 6.8) Concentrate
SS-171A-EU	Hematology Reagent A Buffer (pH 6.8) Concentrate
SS-171B2	Hematology Thiazin Stain Concentrate, 200 mL
SS-171C2	Hematology Eosin Stain Concentrate, 220 mL
SS-172A	Hematology Buffer (pH7.2) Concentrate, 30 mL
SS-172A-EU	Hematology Buffer (pH 7.2) Concentrate, 30 mL

**And therefore bears the CE and IVD markings.**

A technical file is maintained at ELITechGroup Inc. Biomedical System Division located at 370 West 1700 South, Logan, Utah, 84321, USA and a copy is provided to our European Authorized Representative.





Dawn T. Perdue  
Director of Quality Assurance



Date



Location