

EC DECLARATION OF CONFORMITY

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This declaration is issued under the sole responsibility of the manufacturer, that the following products:

Product Name: Aerospray® Hematology Pro Slide Stainer/Cytocentrifuge
Model Number: Model 7152
Basic UDI-DI: 3661540AerosprayG8
Intended Purpose: The Aerospray Hematology Pro Slide Stainer/Cytocentrifuge (Model 7152) is intended for use by medical professionals to stain specimens that may include blood and other body fluids, as a step of standard laboratory practice in diagnosing disease. The optional Cytopro rotors allows preparation of slides by cytocentrifugation before staining.
UDI-DI: 03661540303944
GMDN Code: 15599
EMDN Code: W0202059002
Device Classification: Class A

Covered by this present declaration conform to the requirements of Regulation (EU) 2017/746 of the European Parliament and of the Council on *in vitro* diagnostic medical devices, associated General Safety and Performance Requirements as set out in Annex I, and RoHS 2 Directive, (2011/65/EU).

Conformity assessment was performed following the requirements of Article 48, Section 10 of Regulation (EU) 2017/746 of the European Parliament and of the Council on *in vitro* diagnostic medical devices.

The following standards were applied:

EN ISO 13485:2016	EN 61010-1:2010/A1:2019
EN ISO 14971:2012	EN 61010-2-020:2017
IEC 62366-1:2015	EN 61010-2-101:2017
IEC 62304:2006/AMD1:2015	EN 61326-1:2013
EN ISO 23640:2015	EN 55011:2009 A1:2010 (CISPR 11 (2008)A1(2009))
EN ISO 15223-1:2021	
EN ISO 18113-1:2011	
EN ISO 18113-2:2011	
EN ISO 18113-3:2011	

The accessories listed hereafter conform the requirements of Regulation (EU) 2017/746 of the European Parliament and of the Council on *in vitro* diagnostic medical devices and associated General Safety and Performance Requirements as set out in Annex I.

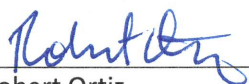
Model Number	Description	GMDN	EMDN	Basic UDI-DI	UDI	Risk Class
AC-160	Cytopro® Rotor	35881	W02069004	3661540AerosprayG8	03661540301179	Class A
AC-188	Aerospray® 12 Slide Carousel	15599	W0202059002	3661540AerosprayG8	03661540300011	Class A
AC-189	Aerospray® 30 Slide Carousel	15599	W0202059002	3661540AerosprayG8	03661540300028	Class A
Stains and Cleaning Solutions						
SS-029	Aerospray® Nozzle Cleaning Solution, 355mL	59058	W01030199	3661540Aerospray-StainXL	03661540302114	Class A
SS-029C	Aerospray® Nozzle Cleaning Solution Concentrate, 250mL	59058	W01030199	3661540Aerospray-StainXL	03661540302121	Class A
SS-029C-EU	Aerospray® Nozzle Cleaning Solution Concentrate, 250mL	59058	W01030199	3661540Aerospray-StainXL	03661540303876	Class A
SS-048	Aerospray® Hematology Reagent D, Aerofix® Fixative, 500mL	43587	W0103010302	3661540Aerospray-StainXL	03661540302350	Class A
SS-071A	Aerospray® Hematology Pro Reagent A, Buffer (pH 6.8), 1Gal	43587	W0103010302	3661540Aerospray-StainXL	03661540302558	Class A
SS-071B	Aerospray® Hematology Pro Reagent B, Thiazin Stain, 500mL	43587	W0103010302	3661540Aerospray-StainXL	03661540302565	Class A
SS-071B-EU	Aerospray® Hematology Pro Reagent B, Thiazin Stain, 500mL	43587	W0103010302	3661540Aerospray-StainXL	03661540303791	Class A
SS-071C	Aerospray® Hematology Pro Reagent C, Eosin Stain, 500mL	43587	W0103010302	3661540Aerospray-StainXL	03661540302572	Class A
SS-071C-EU	Aerospray® Hematology Pro Reagent C, Eosin Stain, 500mL	43587	W0103010302	3661540Aerospray-StainXL	03661540303807	Class A
SS-072A	Aerospray® Hematology Pro Reagent A, Buffer (pH 7.2), 1Gal	43587	W0103010302	3661540Aerospray-StainXL	03661540302589	Class A
SS-072A-EU	Aerospray® Hematology Pro Reagent A, Buffer (pH 7.2), 1Gal	43587	W0103010302	3661540Aerospray-StainXL	03661540303784	Class A
SS-148	Aerospray® Hematology Reagent D, Aerofix® Fixative concentrate, 135mL	43587	W0103010302	3661540Aerospray-StainXL	03661540302954	Class A
SS-148-EU	Aerospray® Hematology Reagent D, Aerofix® Fixative concentrate, 135mL	43587	W0103010302	3661540Aerospray-StainXL	03661540303845	Class A
SS-171A	Aerospray® Hematology Pro Reagent A, Buffer (pH 6.8) Concentrate, 30mL	43587	W0103010302	3661540Aerospray-StainXL	03661540303098	Class A
SS-171A-EU	Aerospray® Hematology Pro Reagent A, Buffer (pH 6.8) Concentrate, 30mL	43587	W0103010302	3661540Aerospray-StainXL	03661540303814	Class A
SS-171B2	Aerospray® Hematology Pro Reagent B, Thiazin Stain Concentrate, 200mL	43587	W0103010302	3661540Aerospray-StainXL	03661540303074	Class A
SS-171C2	Aerospray® Hematology Pro Reagent C, Eosin Stain Concentrate, 220mL	43587	W0103010302	3661540Aerospray-StainXL	03661540303081	Class A
SS-172A	Aerospray® Hematology Pro Reagent A, Buffer (pH 7.2) Concentrate, 30mL	43587	W0103010302	3661540Aerospray-StainXL	03661540303050	Class A

SS-172A-EU	Aerospray® Hematology Pro Reagent A, Buffer (pH 7.2) Concentrate, 30mL	43587	W0103010302	3661540Aerospray-StainXL	03661540303821	Class A
SS-222	Aerospray® Line Cleaner, 250mL	59058	W01030199	3661540Aerospray-StainXL	03661540303210	Class A
SS-230	Aerospray® Stain Residue Solvent, 500mL	59058	W01030199	3661540Aerospray-StainXL	03661540303630	Class A
SS-230-EU	Aerospray® Stain Residue Solvent, 500mL	59058	W01030199	3661540Aerospray-StainXL	03661540304354	Class A
SS-266	Aerospray® PM Cleaning Solution, 500mL	59058	W01030199	3661540Aerospray-StainXL	03661540304057	Class A
SS-266-EU	Aerospray® PM Cleaning Solution, 500mL	59058	W01030199	3661540Aerospray-StainXL	03661540304064	Class A
SS-MeOH	Aerospray® Reagent Grade Methanol, 500mL	43587	W0103010302	3661540Aerospray-StainXL	03661540303289	Class A

And therefore, bears the CE Marking.

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




 Robert Ortiz
 Regulatory Affairs Manager
 on behalf of ELITechGroup Inc.

2023/06/07
 Date

Logan, Utah
 Location