

## EC DECLARATION OF CONFORMITY

**Manufacturer's Name:** ELITechGroup Inc.  
SRN: US-MF-000006942

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SRN: DE-AR-000000085

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

**Product Name:** Aerospray® Gram Slide Stainer/Cytocentrifuge  
**Model Number:** Model 7322  
**Basic UDI-DI:** 3661540AerosprayG8  
**Intended Purpose:** The Aerospray Gram stainer is an in vitro diagnostic medical device for professional use only. The Gram stainer has been designed to perform automated Gram staining of pure strain isolate smears and other specimens with microorganisms for in vitro diagnostics with ELITechGroup Gram reagents only.

**UDI-DI** 03661540303951  
**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
<b>Stains and Cleaning Solutions</b>						
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-041A	Aerospray® Gram Reagent A Decolorizer with Safranin, 500mL	43587	W0104010804	3661540Aerospray-StainXL	03661540302275	Class A
SS-041A-EU	Aerospray® Gram Reagent A Decolorizer with Safranin, 500mL	43587	W0104010804	3661540Aerospray-StainXL	03661540303654	Class A
SS-041AA	Aerospray® Gram Reagent A, Decolorizer with Acetone and Safranin, 500m	43587	W0104010804	3661540Aerospray-StainXL	03661540302282	Class A
SS-041AA-EU	Aerospray® Gram Reagent A, Decolorizer with Acetone and Safranin, 500mL	43587	W0104010804	3661540Aerospray-StainXL	03661540303661	Class A
SS-041AAF	Aerospray® Gram Reagent A, Decolorizer with Acetone and Fuchsin 500mL	43587	W0104010804	3661540Aerospray-StainXL	03661540303647	Class A
SS-041AAF-EU	Aerospray® Gram Reagent A, Decolorizer with Acetone and Fuchsin 500mL	43587	W0104010804	3661540Aerospray-StainXL	03661540303685	Class A
SS-041AF	Aerospray® Gram Reagent A, Decolorizer with Fuchsin 500mL	43587	W0104010804	3661540Aerospray-StainXL	03661540302299	Class A
SS-041AF-EU	Aerospray® Gram Reagent A, Decolorizer with Fuchsin 500mL	43587	W0104010804	3661540Aerospray-StainXL	03661540303678	Class A
SS-041B	SS-041B Aerospray® Gram Reagent B, Iodine, 500mL	43587	W0104010804	3661540Aerospray-StainXL	03661540302305	Class A
SS-041B-EU	SS-041B Aerospray® Gram Reagent B, Iodine, 500mL	43587	W0104010804	3661540Aerospray-StainXL	03661540303692	Class A

SS-041C	Aerospray® Gram Reagent C, Crystal Violet, 500mL	43587	W0104010804	3661540Aerospray-StainXL	03661540302312	Class A
SS-041C-EU	Aerospray® Gram Reagent C, Crystal Violet, 500mL	43587	W0104010804	3661540Aerospray-StainXL	03661540303708	Class A
SS-141A	SS-141A Aerospray® Gram Reagent A, Safranin Concentrate, 210mL	43587	W0104010804	3661540Aerospray-StainXL	03661540302893	Class A
SS-141AF	SS-141AF Aerospray® Gram Reagent A, Fuchsin Concentrate, 135mL	43587	W0104010804	3661540Aerospray-StainXL	03661540302909	Class A
SS-141B	SS-141B Aerospray® Gram Reagent B, Iodine Concentrate, 500mL	43587	W0104010804	3661540Aerospray-StainXL	03661540302916	Class A
SS-141C	SS-141C Aerospray® Gram Reagent C, Crystal Violet Concentrate 135mL	43587	W0104010804	3661540Aerospray-StainXL	03661540302923	Class A
SS-MeOH	Aerospray® Reagent Grade Methanol, 500mL	59058	W0103010302	3661540Aerospray-StainXL	03661540303289	Class A
SS-250	Gram Stain Control Slides, Qty 50	43510	W02039085	3661540AerosprayG8	03661540303999	Class A
SS-250SAM	Gram Stain Control Slides, Qty 10	43510	W02039085	3661540AerosprayG8	03661540300387	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  
 Robert Ortiz  
 Regulatory Affairs Manager  
 on behalf of ELITechGroup Inc.

2023/06/07  
 Date

Logan, Utah  
 Location