

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® TB Slide Stainer/Cytocentrifuge
Model Number: Model 7722
Basic UDI-DI: 3661540AerosprayG8
Intended Purpose: The Aerospray® TB Slide Stainer/Cytocentrifuge (Model 7722) is a dual-purpose stainer intended for in vitro diagnostic use by medical professionals to stain microbiological specimens suspected of containing acid-fast organisms, a step in the standard laboratory practice of diagnosing disease. The use of Aerospray® TB reagents is required for successful use of this instrument. Adding the optional Cytopro® rotor allows preparation of slides by cytocentrifugation before staining.

UDI-DI: 03661540303968
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 ISO 18113-2:2011
EN ISO 14971:2012	EN ISO 18113-3:2011
IEC 62366-1:2015	EN 61010-1:2010/A1:2019
IEC 62304:2006/AMD1:2015	EN 61010-2-020:2017
EN ISO 23640:2015	EN 61010-2-101:2017
EN ISO 15223-1:2021	EN 61326-1:2013
EN ISO 18113-1:2011	EN 55011:2009 A1:2010 (CISPR 11 (2008)A1(2009))

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, 355 mL	59058	W01030199	3661540Aerospray-StainXL	03661540302114	Class A
SS-029C	Aerospray® Nozzle Cleaning Solution Concentrate, 250 mL	59058	W01030199	3661540Aerospray-StainXL	03661540302121	Class A
SS-029C-EU	Aerospray® Nozzle Cleaning Solution Concentrate, 250 mL	59058	W01030199	3661540Aerospray-StainXL	03661540303876	Class A
SS-061A	Aerospray® TB Reagent A, Carbol Fuchsin Decolorizer, 500mL	43587	W0104010804	3661540Aerospray-StainXL	03661540302459	Class A
SS-061A-EU	Aerospray® TB Reagent A, Carbol Fuchsin Decolorizer, 500mL	43587	W0104010804	3661540Aerospray-StainXL	03661540303449	Class A
SS-061AF	Aerospray® TB Reagent A, Fluorescence Decolorizer, 500mL	43587	W0104010804	3661540Aerospray-StainXL	03661540302466	Class A
SS-061AF-EU	Aerospray® TB Reagent A, Fluorescence Decolorizer, 500mL	43587	W0104010804	3661540Aerospray-StainXL	03661540303456	Class A
SS-061BBG	Aerospray® TB Reagent B, Brilliant Green, 500mL	43587	W0104010804	3661540Aerospray-StainXL	03661540302473	Class A
SS-061BBG-EU	Aerospray® TB Reagent B, Brilliant Green, 500mL	43587	W0104010804	3661540Aerospray-StainXL	03661540303463	Class A
SS-061BCS-EU	Aerospray® TB Reagent B, Carbol Fuchsin, 500mL	43587	W0104010804	3661540Aerospray-StainXL	03661540303470	Class A
SS-061BMB	Aerospray® TB Reagent B, Methylene Blue, 500mL	43587	W0104010804	3661540Aerospray-StainXL	03661540302480	Class A
SS-061BMB-EU	Aerospray® TB Reagent B, Methylene Blue, 500mL	43587	W0104010804	3661540Aerospray-StainXL	03661540303487	Class A
SS-061BP	Aerospray® TB Reagent B, Potassium Permanganate, 500mL	43587	W0104010804	3661540Aerospray-StainXL	03661540302497	Class A

SS-061BP-EU	Aerospray® TB Reagent B, Potassium Permanganate, 500mL	43587	W0104010804	3661540	Aerospray-StainXL	03661540303494	Class A
SS-061BRT-EU	Aerospray® TB Reagent B, Thiazin Red, 500 mL	43587	W0104010804	3661540	Aerospray-StainXL	03661540303517	Class A
SS-061CA	Aerospray® TB Reagent C, Auramine O, 500mL	43587	W0104010804	3661540	Aerospray-StainXL	03661540302503	Class A
SS-061CA-EU	Aerospray® TB Reagent C, Auramine O, 500mL	43587	W0104010804	3661540	Aerospray-StainXL	03661540303524	Class A
SS-061CAR	Aerospray® TB Reagent C, Auramine/Rhodamine (mod), 500mL	43587	W0104010804	3661540	Aerospray-StainXL	03661540302510	Class A
SS-061CAR-EU	Aerospray® TB Reagent C, Auramine/Rhodamine (mod), 500mL	43587	W0104010804	3661540	Aerospray-StainXL	03661540303531	Class A
SS-061CEZ	Aerospray® TB Reagent C, ELITe ZN, 500mL	43587	W0104010804	3661540	Aerospray-StainXL	03661540304002	Class A
SS-061CEZ-EU	Aerospray® TB Reagent C, ELITe ZN, 500mL	43587	W0104010804	3661540	Aerospray-StainXL	03661540304019	Class A
SS-061M	Aerospray® TB, Mycohold™ Cell Adhesive, 500mL	43587	W0104010804	3661540	Aerospray-StainXL	03661540302541	Class A
SS-061M-EU	Aerospray® TB, Mycohold™ Cell Adhesive, 500mL	43587	W0104010804	3661540	Aerospray-StainXL	03661540303838	Class A
SS-082-EU	Aerofix® for Aerospray® Gram and TB Stainers	43587	W0104010804	3661540	Aerospray-StainXL	03661540303869	Class A
SS-161A	Aerospray® TB Reagent A, Carbol Fuchsin Decolorizer Concentrate, 30mL	43587	W0104010804	3661540	Aerospray-StainXL	03661540302992	Class A
SS-161AF	Aerospray® TB Reagent A, Fluorescence Decolorizer Concentrate, 30mL	43587	W0104010804	3661540	Aerospray-StainXL	03661540303005	Class A
SS-161BBG	Aerospray® TB Reagent B, Brilliant Green Concentrate, 130mL	43587	W0104010804	3661540	Aerospray-StainXL	03661540303012	Class A
SS-161BMB	Aerospray® TB Reagent B, Methylene Blue Concentrate, 130 mL	43587	W0104010804	3661540	Aerospray-StainXL	03661540303029	Class A
SS-161BP	Aerospray® TB Reagent B, Potassium Permanganate Concentrate, 200mL	43587	W0104010804	3661540	Aerospray-StainXL	03661540303036	Class A
SS-161M	Aerospray® TB, Mycohold™ Cell Adhesive Concentrate, 100mL	43587	W0104010804	3661540	Aerospray-StainXL	03661540303043	Class A
SS-266	Aerospray® PM Cleaning Solution, 500mL	59058	W01030199	3661540	Aerospray-StainXL	03661540304057	Class A
SS-266-EU	Aerospray® PM Cleaning Solution, 500mL	59058	W01030199	366154	AerosprayStainXL	03661540304064	Class A
SS-MeOH	Aerospray® Reagent Grade Methanol, 500mL	57724	W0103010302	3661540	Aerospray-StainXL	03661540303289	Class A

SS-249	AFB/TB Stain Control Slides, Qty 50	43510	W02039085	3661540AerosprayG8	03661540303982	Class A
SS-249SAM	AFB/TB Stain Control Slides, Qty 10	43510	W02039085	3661540AerosprayG8	03661540300394	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