

HORIBA ABX SAS

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EU Declaration of Conformity

(N° dc90133ben)

WE THE MANUFACTURER

Name	HORIBA ABX SAS
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Single Registration Number	FR-MF-000000320

TAKE SOLE RESPONSIBILITY FOR AND HEREBY DECLARE THAT THE PRODUCT(S)

Device category	Hematology Analyzer
Product name	Yumizen SPS
Basic UDI-DI	361023ymz_spsXJ
Country of origin	FRANCE

Intended Use

The Yumizen SPS is a Slide Preparation System which smears and stains blood on a clean microscope slide in conjunction with an instrument from the Yumizen H1500 and Yumizen H2500 family in clinical laboratories. The Yumizen SPS can run the following operations:

- SMEAR: preparation of a sample blood smear,
- STAIN: preparation and/or staining of a sample blood smear.

MEET(S) THE PROVISIONS OF THE FOLLOWING DIRECTIVES, REGULATIONS, STANDARDS AND COMMON SPECIFICATIONS

Regulations	Regulation (EU) 2017/746 on <i>in vitro</i> diagnostic medical devices Risk Class: A ☒ B ☐ C ☐ D ☐
IVDR conformity assessment route	☒ ANNEX II + ANNEX III + ANNEX IV (<i>Class A devices excluding sterile devices</i>)
Directives	2011/65/EU - Amended by 2015/863/EU - ROHS Directive Category: 8- Medical Devices
Standards	IEC 61010-1: 2010 / IEC 61010-2-081: 2019 / IEC 61010-2-101: 2019 / UL 61010-1: 2012 / UL 61010-2-081: 2019 / UL 61010-2-101: 2019 / CAN/CSA-C22.2 No. 61010-1-12 + GI1 + GI2 (R2017) / No. 61010-2-081: 19 / No. 61010-2-101: 19 / IEC 61326-1: 2012 / IEC 61326-2-6: 2012 / IEC 60601-1-2: 2014 / EN IEC 63000: 2018
Common Specifications	Not applicable

Montpellier, France
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Claire MALLIÉ
Quality & Regulatory Affairs Junior
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