

Declaration of Conformity

(dc50004aen)

WE THE MANUFACTURER

Name	HORIBA ABX SAS
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TAKE SOLE RESPONSIBILITY FOR AND HEREBY DECLARE THAT THE PRODUCT(S)

Device category	Veterinary Hematology Analyzer
Product name	Yumivet SPS
Country of origin	FRANCE

Intended Use

The Yumivet SPS is a Slide Preparation System which smears and stains blood on a clean microscope slide in conjunction with an instrument from the Yumivet VH2500 family in clinical laboratories.

The Yumivet 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: Not applicable, device for veterinary use only.
Directives	2011/65/EU - Amended by 2015/863/EU - ROHS Directive Category: 8-Medical Devices
Standards	IEC 61010-1: 2010 + A1 / IEC 61010-2-101: 2018 / IEC 61326-1: 2020 / IEC 61326-2-6: 2020 / IEC 60601-1-2: 2020 / EN IEC 63000: 2018
Common Specifications	Not applicable

Montpellier, France
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Claire MALLIÉ

Quality, Regulatory Affairs & Information
Systems Director / PRRC

