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Declaration of Conformity

(dc50003aen)

WE THE MANUFACTURER

Name	**HORIBA ABX SAS**
 Address	Parc Euromédecine Rue du Caducée BP 7290 34184 Montpellier Cedex 4 FRANCE

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

Device category	**Veterinary Hematology Analyzer**
Product name	**Yumivet VH2500**
Country of origin	**FRANCE**

Intended Use

The Yumivet VH2500 is a quantitative multiparameter fully automated hematology analyzer intended for *in-vitro* diagnostic in veterinary practice testing.
The Yumivet VH2500 is intended to perform tests on the following specimens:

- Anticoagulated whole blood specimens.
- Body fluids (synovial fluids, serous fluids (peritoneal, pericardial, pleural fluids) and cerebrospinal fluids).

The Yumivet VH2500 classifies and enumerates the following parameters:

- A complete blood count (CBC) consisting of TNC, WBC, RBC, HGB, Calculated HCT, MCV, calculated MCH, calculated MCHC, RDW-SD, RDW-CV, PLT, PLT-Ox, LPF, MPV, PDW, PCT, MIC, MAC, P-LCC, P-LCR.
- A leukocyte differential count consisting of LYM (%/#), MON (%/#), NEU (%/#), EOS (%/#), BAS (%/#), ALY (%/#), LIC (%/#), IML (%/#), IMM (%/#), IMG (%/#).
- A nucleated red blood cell count consisting of NRBC (%/#).
- A reticulocyte analysis consisting of RET (%/#), calculated CRC, IRF, calculated RHCC, MRV, RET-L, RET-M, RET-H.
- Quantitative determination of blood cells in synovial fluids, serous fluids (peritoneal, pericardial, pleural fluids) and cerebrospinal fluids consisting of BFWBC, BFRBC, BFPN (%/#), BFMN (%/#).

In addition, the analyzer Yumivet VH2500 with the Yumivet SPS option provides the added capability to automatically prepare and stain high quality blood smears on a glass microscope slide.

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

Regulations	Regulation (EU) 2017/746 on *in vitro* 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