HORIBA ABX SAS
Parc Euromédecine
Rue du Caducée - BP 7290
34184 Montpellier Cedex 4 - FRANCE
Phone: +33 (0)4 67 14 15 16
Web: www.horiba.com

EU Declaration of Conformity

(HELO 2.X N°dc90017den)

WE THE MANUFACTURER

Name	**HORIBA ABX SAS**
 Address	Parc Euromédecine Rue du Caducée BP 7290 34184 Montpellier Cedex 4 FRANCE
Single Registration Number	FR-MF-000000320

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

Device category	**Hematology Analyzer**
Product name	**Yumizen H1500 / Yumizen H2500**
Basic UDI-DI	**361023ymz_h1500JQ / 361023ymz_h2500JX**
Country of origin	**FRANCE**

Intended Use

The Yumizen H1500 is a quantitative multiparameter fully automated hematology analyzer intended for *in-vitro* diagnostic use in clinical laboratories by qualified healthcare professionals for the screening of patient populations.
The Yumizen H1500 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 Yumizen H1500 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, 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 (%/#).
- 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 with the Yumizen SPS option provides the added capability to automatically prepare and stain high quality blood smears on a glass microscope slide.

Venous and capillary whole blood should be collected in K2-EDTA or K3-EDTA anticoagulant.
Synovial and serous fluids should be collected in K2-EDTA anticoagulant.
The use of anticoagulants with cerebrospinal fluid specimens is neither required nor recommended.
Viscous synovial fluids can be liquefied by adding hyaluronidase.

The Yumizen H2500 is a quantitative multiparameter fully automated hematology analyzer intended for in-vitro diagnostic use in clinical laboratories by qualified healthcare professionals for the screening of patient populations.
The Yumizen H2500 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 Yumizen H2500 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 with the Yumizen SPS option provides the added capability to automatically prepare and stain high quality blood smears on a glass microscope slide.

Venous and capillary whole blood should be collected in K2-EDTA or K3-EDTA anticoagulant.
Synovial and serous fluids should be collected in K2-EDTA anticoagulant.
The use of anticoagulants with cerebrospinal fluid specimens is neither required nor recommended.
Viscous synovial fluids can be liquefied by adding hyaluronidase.

HORIBA

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: A** ☐ **B** ☒ **C** ☐ **D** ☐	
IVDR conformity assessment route	☒ ANNEX IX (Chap I & III, chap II section 4) + ANNEX IV *(Class B & C devices excluding self-testing and near patient testing devices)*	EU CERTIFICATE #: IVDR 745367 Name of Notified Body: BSI Group The Netherlands B.V. Notified Body Identification: 2797
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	
Common Specifications	Not applicable	

Montpellier, France
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Claire MALLIÉ
Quality & Regulatory Affairs Junior Director / PRRC

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