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EU Declaration of Conformity

(HELO 1.X N°dc90165cen)

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 H2500 is a quantitative multi-parameters, fully automated hematology analyzer used for *in vitro* diagnostic testing of the following specimens:

- anticoagulated whole blood specimens
- body fluids (synovial fluids, serous fluids (peritoneal, pericardial, pleural fluids) and cerebrospinal fluids)

It is used for screening a physiological state (quantitative or qualitative hematology abnormality detection) or a pathological state of patient populations found in clinical laboratories.

The Yumizen H2500 classifies and enumerates the following parameters:
WBC, TNC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW-CV, RDW-SD, MIC, MAC, PLT, PLT-Ox, MPV, PCT, PDW, NRBC#, NRBC%, LYM#, LYM%, MON#, MON%, NEU#, NEU%, EOS#, EOS%, BAS#, BAS%, ALY#, ALY%, LIC#, LIC%, IML#, IML%, IMM#, IMM%, IMG#, IMG%, BFRBC, BFWBC, BFMN#, BFMN%, BFPN#, BFPN%, RET#, RET%, RETL, RETM, RETH, CRC, MRV, MFI, IRF, RHCC, PIC.

The Yumizen H1500 is a quantitative multi-parameters, fully automated hematology analyzer used for *in vitro* diagnostic testing of the following specimens:

- anticoagulated whole blood specimens
- body fluids (synovial fluids, serous fluids (peritoneal, pericardial, pleural fluids) and cerebrospinal fluids)

It is used for screening a physiological state (quantitative or qualitative hematology abnormality detection) or a pathological state of patient populations found in clinical laboratories.
The Yumizen H1500 classifies and enumerates the following parameters:
WBC, TNC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW-CV, RDW-SD, MIC, MAC, PLT, MPV, PCT, PDW, NRBC#, NRBC%, LYM#, LYM%, MON#, MON%, NEU#, NEU%, EOS#, EOS%, BAS#, BAS%, ALY#, ALY%, LIC#, LIC%, IML#, IML%, IMM#, IMM%, IMG#, IMG%, BFRBC, BFWBC, BFMN#, BFMN%, BFPN#, BFPN%.

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 61010-2-081: 2019 / IEC 61010-2-101: 2018 / EN 61326-1: 2012 / EN 61326-2-6: 2012	
Common Specifications	Not applicable	

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