

**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](http://www.horiba.com)

## EU Declaration of Conformity

(N° dc90165ben)

### WE THE MANUFACTURER

|                                                                                              |                                                                                       |
|----------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------|
| Name                                                                                         | <b>HORIBA ABX SAS</b>                                                                 |
| <br>Address | Parc Euromédecine<br>Rue du Caducée<br>BP 7290<br>34184 Montpellier Cedex 4<br>FRANCE |
| Single Registration Number                                                                   | FR-MF-000000320                                                                       |

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

|                   |                                                  |
|-------------------|--------------------------------------------------|
| Device category   | <b>Hematology Analyzer</b>                       |
| Product name      | <b>Yumizen H1500 / Yumizen H2500</b>             |
| Basic UDI-DI      | <b>361023ymz_h1500JQ /<br/>361023ymz_h2500JX</b> |
| Country of origin | <b>FRANCE</b>                                    |

### 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 <i>in vitro</i> diagnostic medical devices<br><b>Risk Class:</b> A <input type="checkbox"/> B <input checked="" type="checkbox"/> C <input type="checkbox"/> D <input type="checkbox"/> |                                                                                                                             |
| IVDR conformity assessment route | <input checked="" type="checkbox"/> ANNEX IX (Chap I & III, chap II section 4) + ANNEX IV ( <i>Class B &amp; C devices excluding self-testing and near patient testing devices</i> )                                | EU CERTIFICATE #: IVDR 745367<br>Name of Notified Body: BSI Group The Netherlands B.V<br>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  
2024/09/23

**Claire MALLIÉ**  
Quality & Regulatory Affairs Junior  
Director / PRRC