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EU Declaration of Conformity

(N° dc90162aen)

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 H550 / Yumizen H500 CT / Yumizen H500 OT**
Basic UDI-DI	**361023ymz_h500_otMW / 361023ymz_h500_ctLS / 361023ymz_H550T2**
Country of origin	**FRANCE**

Intended Use

The Yumizen H550 / Yumizen H500 CT / Yumizen H500 OT classifies and enumerates the following parameters in whole blood:
WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW-CV, RDW-SD, MIC, MAC, PLT, MPV, PCT, PDW, P-LCC, P-LCR, LYM#, LYM%, MON#, MON%, NEU#, NEU%, EOS#, EOS%, BAS#, BAS%, ALY#, ALY%, LIC#, LIC%, IML#, IML%, IMM#, IMM%, IMG#, IMG%.
The Yumizen H550 / Yumizen H500 CT / Yumizen H500 OT provides information for *in vitro* diagnostic use in clinical laboratories.
The Yumizen H550 / Yumizen H500 CT / Yumizen H500 OT analyzer is used for screening a physiological state (quantitative or qualitative hematology abnormality detection) or a pathological state of patient populations found in clinical laboratories.

HORIBA Medical

The Yumizen H550 / Yumizen H500 CT / Yumizen H500 OT analyzer is quantitative for parameters measurement and qualitative for alarms detection.
The Yumizen H550 / Yumizen H500 CT / Yumizen H500 OT analyzer is intended to perform tests on the following specimens:

- venous blood
- capillary blood

collected in K2-EDTA and K3-EDTA anticoagulants.
The Yumizen H550 / Yumizen H500 CT / Yumizen H500 OT analyzer is intended to perform tests on the following specimens:
Pediatric

- New born: from birth to 28 days
- Infant: from 29 days to 2 years
- Children: from 2 years to 12 years
- Adolescent: from 12 years to 18 years

Adult population

- Above 18 years

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 - RoHS Restriction of Hazardous Substances (Classification: Category 8 Medical Device)	
Standards	IEC 61010-1: 2010 + A1 / EN 61326-2-6: 2020 / IEC 60601-1-2: 2020	
Common Specifications	Not applicable	

Montpellier, France
2024/07/15

Claire MALLIÉ
Quality & Regulatory Affairs Junior Director / PRRC

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