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EU Declaration of Conformity

(N° dc90177aen)

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 H500 CRP**
Basic UDI-DI	**361023ymz_h500CRPDY**
Country of origin	**FRANCE**

Intended Use

The Yumizen H500 CRP 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%, CRP.
The Yumizen H500 CRP provides information for *in vitro* diagnostic use in clinical laboratories.
The Yumizen H500 CRP 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.
The Yumizen H500 CRP analyzer is quantitative for parameters measurement and qualitative for alarms detection.
The Yumizen H500 CRP analyzer is intended to perform tests on the following specimens:

- venous blood
- capillary blood
- plasma from vein for CRP measurement collected in K2-EDTA and K3-EDTA anticoagulant
- serum from vein for CRP measurement collected on tube without anticoagulant

The Yumizen H500 CRP analyzer is intended to perform tests on adult and pediatric specimens.

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 - RoHS Restriction of Hazardous Substances (Classification: Category 8 Medical Device)	
Standards	EN IEC 61326-2-6: 2022 / EN IEC 61000-3-2: 2019 / EN IEC 61000-3-3: 2013 + A1 / IEC 61010-1: 2010 + A1 / EN IEC 61010-2-101: 2022	
Common Specifications	Not applicable	

Montpellier, France
2025/12/18

Claire MALLIÉ
Quality & Regulatory Affairs Junior Director / PRRC

TEMP-5695 Rev.005