

EU Declaration of Conformity

(N° dc90160aen)

WE THE MANUFACTURER

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Single Registration Number	FR-MF-000000320

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

Device category	Hematology Analyzer
Product name	Yumizen H550E / Yumizen H500E CT / Yumizen H500E OT
Basic UDI-DI	361023ymz_H550ELU / 361023ymz_h500E_ctRV / 361023ymz_h500E_otSZ
Country of origin	FRANCE

Intended Use

The Yumizen H550E / Yumizen H500E CT / Yumizen H500E 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%, ESR.

The Yumizen H550E / Yumizen H500E CT / Yumizen H500E OT provides information for *in vitro* diagnostic use in clinical laboratories.

The Yumizen H550E / Yumizen H500E CT / Yumizen H500E 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.

The Yumizen H550E / Yumizen H500E CT / Yumizen H500E OT analyzer is quantitative for parameters measurement and qualitative for alarms detection.

The Yumizen H550E / Yumizen H500E CT / Yumizen H500E OT analyzer is intended to perform tests on the following specimens:

- venous blood (CBC / DIFF / ESR)
- capillary blood (CBC / DIFF)

collected in K2-EDTA and K3-EDTA anticoagulants.

The Yumizen H550E / Yumizen H500E CT / Yumizen H500E OT analyzer is intended to perform tests on the following specimens:

Pediatric

- New born: from birth to 28 days (only: CBC / DIFF)
- Infant: from 29 days to 2 years (only: CBC / DIFF)
- Children: from 2 years to 12 years (CBC / DIFF / ESR)
- Adolescent: from 12 years to 18 years (CBC / DIFF / ESR)

Adult population

- Above 18 years (CBC / DIFF / ESR)

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 Risk Class: A ☐ B ☒ C ☐ D ☐	
IVDR conformity assessment route	☒ ANNEX IX (Chap I & III, chap II section 4) + ANNEX IV (<i>Class B & C devices excluding self-testing and near patient testing devices</i>)	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 / EN 61326-2-6: 2020 / IEC 60601-1-2: 2020	
Common Specifications	Not applicable	

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