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EU Declaration of Conformity

(N° dc90150ben)

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 P8000**
Basic UDI-DI	**361023ymz_p8000N8**
Country of origin	**ITALY**

Intended Use

The Yumizen P8000 is a data manager connected between one (or more) in vitro diagnostic instrument(s) and the Laboratory Information System.
The Yumizen P8000 is to be used in clinical laboratories:

- Review, validate and manage patient and quality control results
- Help the flow of laboratory information, including test orders and results

HORIBA Medical

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 II + ANNEX III + ANNEX IV *(Class A devices excluding sterile devices)*
Directives	2011/65/EU - Amended by 2015/863/EU - ROHS Directive Category: 8- Medical Devices
Standards	EN IEC 63000: 2018
Common Specifications	Not applicable

Montpellier, France
2022/09/12

Claire MALLIÉ
Quality & Regulatory Affairs Junior Director / PRRC

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