**HORIBA ABX SAS**
Parc Euromédecine
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# EU Declaration of Conformity

**(N° dc90035ben)**

## WE THE MANUFACTURER

| | |
|---|---|
| Name | **HORIBA ABX SAS** |
|  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 | **Hemostasis Analyzer** |
| Product name | **Yumizen G800** |
| Basic UDI-DI | **361023ymz_g800YQ** |
| Country of origin | **HUNGARY** |

## Intended Use

The Yumizen G800 is a fully automated blood coagulation analyzer.
The instrument can analyze decalcified plasma samples using coagulation, chromogenic and immunoassay methods. The analyzed data can be stored, displayed and reported.
The instrument has several built-in functions, including automatic reagent handling by barcode system, priority processing of STAT samples and quality control.
For *in vitro* diagnostic use only.

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<br>**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 61010-1: 2010 / EN 61010-2-101: 2015 / EN 61326-2-6: 2013 / EN IEC 63000: 2018 |
| Common Specifications | Not applicable |

Montpellier, France
2022/09/06

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

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