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EU Declaration of Conformity

(N° dc90161aen)

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	**Hemostasis Analyzer**
Product name	**Yumizen G405**
Basic UDI-DI	**361023ymz_g405YE**
Country of origin	**HUNGARY**

Intended Use

The Yumizen G405 is a 4-channel semi-automated blood coagulation analyzer.
The instrument can analyze decalcified plasma samples using clotting, chromogenic and immunoturbidimetric methods. The analyzed data can be stored, displayed and reported.
The instrument has several functions, including built-in thermal printer and connectivity to use automatic reagent handling by barcode system.
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 **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: 2011 + A1:2020 / EN 61010-2-101: 2017 / EN 61326-1: 2013 / EN 61326-2-6: 2013
Common Specifications	Not applicable

Montpellier, France
2024/07/11

Claire MALLIÉ
Quality & Regulatory Affairs Junior Director / PRRC

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