


## EU Declaration of Conformity

(N° dc90072ben)

### WE THE MANUFACTURER

Name	<b>HORIBA ABX SAS</b>
 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	<b>Hemostasis Analyzer</b>
Product name	<b>Yumizen G400 DDi</b>
Basic UDI-DI	<b>361023ymz_g400Y4</b>
Country of origin	<b>HUNGARY</b>

### Intended Use

The Yumizen G400 DDi is a 4-channel semi-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 functions, including built-in thermal printer and connectivity to use automatic reagent handling by barcode system. For *in vitro* diagnostic use only.

**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 <input checked="" type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D <input type="checkbox"/>
IVDR conformity assessment route	<input checked="" type="checkbox"/> ANNEX II + ANNEX III + ANNEX IV ( <i>Class A devices excluding sterile devices</i> )
Directives	2011/65/EU - Amended by 2015/863/EU - ROHS Directive Category: 8- Medical Devices
Standards	EN 61010-1: 2001 / EN 61010-2-101: 2002 / IEC 61326-2-6: 2005 / EN IEC 63000: 2018
Common Specifications	Not applicable

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