


## EU Declaration of Conformity

(N° dc90139ben)

### WE THE MANUFACTURER

Name	<b>HORIBA ABX SAS</b>
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Single Registration Number	FR-MF-000000320

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

Device category	<b>Hemostasis Accessory</b>
Product name	<b>Yumizen G Cuvettes</b>
Models	<b>1300036425</b>
Basic UDI-DI	<b>361023ymz_g_cuvettesCX</b>
Country of origin	<b>HUNGARY</b>

### Intended Use

**Yumizen G Cuvettes** are single use cuvettes for Yumizen G Line semi-automated and fully automated coagulation analyzers.

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 <b>Risk Class:</b> 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> )
Common Specifications	Not applicable

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

