


EU Declaration of Conformity

(N° dc90136ben)

WE THE MANUFACTURER

Name	HORIBA ABX SAS
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Single Registration Number	FR-MF-000000320

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

Device category	Hemostasis Reagent
Product name	Yumizen G IMIDAZOL
Models	1300036385
Basic UDI-DI	361023ymz_g_imidazol3W
Country of origin	HUNGARY

Intended Use

Yumizen G IMIDAZOL is dilution buffer used as diluting control, calibrator and human sample when performing coagulation tests in decalcified plasma on coagulometry assay, for all human populations.
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>)
Common Specifications	Not applicable

Montpellier, France
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Claire MALLIÉ
Quality & Regulatory Affairs Junior
Director / PRRC

