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EU Declaration of Conformity

(N° dc90088ben)

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 Quality Control**
Product name	**Yumizen G CTRL I & II**
Models	**1300036412**
Basic UDI-DI	**361023ymz_g_contKF**
Country of origin	**HUNGARY**

Intended Use

Yumizen G CTRL I & II is a freeze-dried control plasma, two levels (normal and abnormal), intended to control the following test:

- prothrombin time (PT)
- activated partial thromboplastin time (APTT)
- fibrinogen (FIB)
- thrombin time (TT) (only for Yumizen G CTRL I)
- antithrombin (AT)
- factor FII, FV, FVII, FX
- factor FVIII, FIX, FXI, FXII

HORIBA

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 IX (Chap I & III, chap II section 4) + ANNEX IV *(Class B & C devices excluding self-testing and near patient testing devices)*	EU CERTIFICATE #: IVDR 745367 Name of Notified Body: BSI Group The Netherlands B.V Notified Body Identification: 2797
Common Specifications	Not applicable	

Montpellier, France
2025/08/18

Claire MALLIÉ
Quality & Regulatory Affairs Junior Director / PRRC

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