HORIBA ABX SAS
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EU Declaration of Conformity

(N° dc90074ben)

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 Reagent**
Product name	**Yumizen G CaCl2 4**
Models	**1300036386**
Basic UDI-DI	**361023ymz_g_cacl2RT**
Country of origin	**HUNGARY**

Intended Use

Yumizen G CaCl2 4 is a 0.025 M buffered solution of calcium chloride used as supplementary reagent for various coagulation tests in decalcified plasma on coagulometry assay, for all human populations.
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)*
Common Specifications	Not applicable

Montpellier, France
2022/09/06

Claire MALLIÉ
Quality & Regulatory Affairs Junior Director / PRRC

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