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EU Declaration of Conformity

(N° dc90166aen)

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	**Clinical Chemistry Reagent**
Product name	**Yumizen C Calcium / Yumizen C560 Calcium**
Models	**1300141427 / 1300141428**
Basic UDI-DI	**361023ymz_ccalciumQH / 361023ymz_c560calcium3Y**
Country of origin	**FRANCE**

Intended Use

Yumizen C Calcium / Yumizen C560 Calcium reagent is intended for the quantitative *in vitro* diagnostic determination of calcium in human serum, plasma and urine based on a colorimetric method.
Clinical laboratories use.
Measurement of calcium is used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases and chronic renal disease and tetany (intermittent muscular contractions or spasms).
Measurement of physiological and pathological variations of Calcium in human serum, plasma and urine is useful for screening or follow-up of these diseases and also in the assessment of electrolyte homeostasis and the acid-base balance of the body.

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
2025/07/28

Claire MALLIÉ
Quality & Regulatory Affairs Junior Director / PRRC

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