


EU Declaration of Conformity

(N° dc90170aen)

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	Clinical Chemistry Reagent
Product name	Yumizen C Phosphorus / Yumizen C560 Phosphorus
Models	1300141445 / 1300141446
Basic UDI-DI	361023ymz_cphosphorus7G / 361023ymz_c560phosphorUJ
Country of origin	FRANCE

Intended Use

Yumizen C Phosphorus / Yumizen C560 Phosphorus reagent is intended for the quantitative *in vitro* diagnostic determination of phosphorus in human serum, plasma and urine based on a UV method using phosphomolybdate.

Clinical laboratories use.

Measurements of phosphorus (inorganic) are used in the diagnosis and treatment of various disorders, including parathyroid gland and kidney diseases, and vitamin D imbalance.

Assessing the physiologic and pathologic variations of Phosphorus (inorganic) concentration in human serum and plasma is useful for screening or follow-up of these diseases.

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 type="checkbox"/> B <input checked="" type="checkbox"/> C <input type="checkbox"/> D <input type="checkbox"/>	
IVDR conformity assessment route	<input checked="" type="checkbox"/> ANNEX IX (Chap I & III, chap II section 4) + ANNEX IV (<i>Class B & C devices excluding self-testing and near patient testing devices</i>)	EU CERTIFICATE #: IVDR 745367 Name of Notified Body: BSI Group The Netherlands B.V. Notified Body Identification: 2797
Common Specifications	Not applicable	

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Claire MALLIÉ
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