


EU Declaration of Conformity

(N° dc90169aen)

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 Glucose PAP / Yumizen C560 Glucose PAP
Models	1300141443 / 1300141444
Basic UDI-DI	361023ymz_cglucose_papMF / 361023ymz_c560glu_papCE
Country of origin	FRANCE

Intended Use

Yumizen C Glucose PAP / Yumizen C560 Glucose PAP reagent is intended for the quantitative *in vitro* diagnostic determination of glucose in human serum, plasma and urine using glucose oxidase method by colorimetry.

Clinical laboratories use.

Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.

Assessing physiologic and pathologic variations of glucose concentration in human serum/plasma and urine 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 type="checkbox"/> C <input checked="" 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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Quality & Regulatory Affairs Junior
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