


EU Declaration of Conformity

(N° dc90168aen)

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 Glucose HK / Yumizen C560 Glucose HK
Models	1300141441 / 1300141442
Basic UDI-DI	361023ymz_cglucose_hkRT / 361023ymz_c560glu_hkEZ
Country of origin	FRANCE

Intended Use

Yumizen C Glucose HK / Yumizen C560 Glucose HK reagent is intended for the quantitative *in vitro* diagnostic determination of glucose in human serum, plasma and urine using glucose hexokinase 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.

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	

Montpellier, France
2025/07/28

Claire MALLIÉ
Quality & Regulatory Affairs Junior
Director / PRRC

