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EU Declaration of Conformity

(N° dc90171aen)

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 Urea / Yumizen C560 Urea**
Models	**1300141447 / 1300141448**
Basic UDI-DI	**361023ymz_cureaEC / 361023ymz_c560urea4N**
Country of origin	**FRANCE**

Intended Use

Yumizen C Urea / Yumizen C560 Urea reagent is intended for the quantitative *in vitro* diagnostic determination of urea/urea nitrogen (an end-product of nitrogen metabolism) in human serum, plasma and urine based on an enzymatic UV test using urease and glutamate dehydrogenase.
Clinical laboratories use.
Urea/Urea nitrogen (BUN) measurements are used in the diagnosis and treatment of certain renal and metabolic diseases.
Assessing the physiologic and pathologic variations of Urea/Urea nitrogen (BUN) concentration in human serum, plasma and urine is useful for screening or follow-up of these diseases.

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
2025/07/30

Claire MALLIÉ
Quality & Regulatory Affairs Junior Director / PRRC

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