


EU Declaration of Conformity

(N° dc90172aen)

WE THE MANUFACTURER

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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 Uric Acid / Yumizen C560 Uric Acid
Models	1300141449 / 1300141450
Basic UDI-DI	361023ymz_curic_acidA5 / 361023ymz_c560uric_acid7S
Country of origin	FRANCE

Intended Use

Yumizen C Uric Acid / Yumizen C560 Uric Acid reagent is intended for the quantitative *in vitro* diagnostic determination of uric acid in human serum, plasma and urine based on the enzymatic determination of uric acid using a chromogenic system in the presence of peroxidase and uricase (Trinder method).

Clinical laboratories use.

Uric Acid measurements are used in the diagnosis and treatment of numerous renal and metabolic disorders, including renal failure, gout, leukemia, psoriasis, starvation or other wasting conditions, and of patients receiving cytotoxic drugs.

Assessing the physiologic and pathologic variations of Uric Acid 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 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	

Montpellier, France
2025/07/30

Claire MALLIÉ
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