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EU Declaration of Conformity

(N° dc90184aen)

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 LDL / Yumizen C560 LDL**
Models	**1300148018 / 1300148019**
Basic UDI-DI	**361023ymz_cldlET / 361023ymz_c560ldlMN**
Country of origin	**CANADA**

Intended Use

Yumizen C LDL / Yumizen C560 LDL reagent is intended for the quantitative *in vitro* diagnostic determination of Low Density Lipoprotein Cholesterol (LDL-C) in human serum and plasma based on an enzymatic colorimetric assay with accelerator selective detergent methodology.
Clinical laboratories use.
Lipoprotein measurements are used in the diagnosis and treatment of lipid disorders, atherosclerosis, and various liver and renal diseases.
Assessing physiologic and pathologic variations of Low Density Lipoprotein Cholesterol (LDL-C) concentration in human serum and plasma 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
2026/02/03

Claire MALLIÉ
Quality & Regulatory Affairs Junior Director / PRRC

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