**HORIBA ABX SAS**
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# EU Declaration of Conformity

**(N° dc90183aen)**

## WE THE MANUFACTURER

| | |
|---|---|
| Name | **HORIBA ABX SAS** |
|  Address | Parc Euromédecine<br>Rue du Caducée<br>BP 7290<br>34184 Montpellier Cedex 4<br>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 HDL /<br>Yumizen C560 HDL** |
| Models | **1300148016 / 1300148017** |
| Basic UDI-DI | **361023ymz_chdlE7 /<br>361023ymz_c560hdlM2** |
| Country of origin | **CANADA** |

## Intended Use

**Yumizen C HDL / Yumizen C560 HDL** reagent is intended for the quantitative *in vitro* diagnostic determination of High Density Lipoprotein Cholesterol (HDL-C) in human serum and plasma based on an enzymatic 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 High-Density Lipoprotein Cholesterol (HDL-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<br>**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<br>Name of Notified Body: BSI Group The Netherlands B.V.<br>Notified Body Identification: 2797 |
| Common Specifications | Not applicable | |

Montpellier, France
2026/01/23

**Claire MALLIÉ**
Quality & Regulatory Affairs Junior Director / PRRC

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