


## EU Declaration of Conformity

(N° dc90185aen)

### WE THE MANUFACTURER

Name	<b>HORIBA ABX SAS</b>
 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	<b>Clinical Chemistry Reagent</b>
Product name	<b>Yumizen C Triglycerides / Yumizen C560 Triglycerides</b>
Models	<b>1300148020 / 1300148021</b>
Basic UDI-DI	<b>361023ymz_ctriglyBH / 361023ymz_c560triglyN3</b>
Country of origin	<b>FRANCE</b>

### Intended Use

**Yumizen C Triglycerides / Yumizen C560 Triglycerides** reagent is intended for the quantitative *in vitro* diagnostic determination of triglycerides in human serum and plasma based on an enzymatic colorimetric assay. Clinical laboratories use.

Triglycerides measurements are used in the diagnosis and treatment of patients with diabetes mellitus, nephrosis, liver obstruction, other diseases involving lipid metabolism, or various endocrine disorders.

Assessing the physiologic and pathologic variations of Triglycerides concentration in human serum and plasma 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 <b>Risk Class:</b> 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 &amp; 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	

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