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EU Declaration of Conformity

(N° dc90127cen)

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	**Track System**
Product name	**Yumizen T6000**
Basic UDI-DI	**361023ymz_t6000P6**
Country of origin	**SPAIN**

Intended Use

The Yumizen T6000 is an accessory of in vitro diagnostic medical devices in clinical laboratories.
The Yumizen T6000 is an adaptable conveyor that transports sample tubes between hematology instruments in order to perform required biological tests.

HORIBA Medical

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 II + ANNEX III + ANNEX IV *(Class A devices excluding sterile devices)*
Directives	2011/65/EU - Amended by 2015/863/EU - ROHS Directive Category: 8- Medical Devices
Standards	IEC 60601-1-2: 2014 / IEC 61010-1: 2010 / IEC 61010-2-101: 2018 / EN 61326-1: 2013 / EN 61326-2-6: 2013 / EN IEC 63000: 2018
Common Specifications	Not applicable

Montpellier, France
2023/09/25

Claire MALLIÉ
Quality & Regulatory Affairs Junior Director / PRRC

TEMP-5695 Rev.005