


EU Declaration of Conformity

(N° dc90132ben)

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 Analyzer
Product name	Pentra C400 / Pentra C400 Option I.S.E.
Basic UDI-DI	361023pentra_c40076
Country of origin	FRANCE

Intended Use

The Pentra C400 / Pentra C400 Option I.S.E. system is a fully automated chemistry analyzer using colorimetry, turbidimetry and potentiometry technologies. It is mostly meant to be used for *in vitro* diagnostic analyses based on homogeneous samples such as serum, plasma, urine and whole blood.
 Clinical laboratories use.

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 checked="" type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D <input type="checkbox"/>
IVDR conformity assessment route	<input checked="" type="checkbox"/> ANNEX II + ANNEX III + ANNEX IV (<i>Class A devices excluding sterile devices</i>)
Directives	2011/65/EU - Amended by 2015/863/EU - ROHS Directive Category: 8- Medical Devices
Standards	IEC 61010-1: 2010 / IEC 61010-2-081: 2001+A1 / IEC 61010-2-101: 2002 / EN 61326-1: 2012 / EN 61326-2-6: 2012 / UL 61010-1: 2012 / CAN / CSA-C22.2 NO.61010-1-12 / CAN / CSA-C22.2 NO.61010.2.081-04 (R2009) / CAN/ CSA-C22.2 NO.61010-1-101-04 (R2009) / EN IEC 63000: 2018
Common Specifications	Not applicable

Montpellier, France
2022/09/12

Claire MALLIÉ
Quality & Regulatory Affairs Junior
Director / PRRC