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EU Declaration of Conformity

(N° dc90144ben)

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 C200 / Pentra C200 Option I.S.E.**
Basic UDI-DI	**361023pentra_c2006u**
Country of origin	**CHINA**

Intended Use

The Pentra C200 / Pentra C200 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 and urine.
Clinical laboratories use.

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 - RoHS Restriction of Hazardous Substances (Classification: Category 8 Medical Device)
Standards	IEC 61010-1: 2010 / IEC 61010-2-101: 2015 / IEC 61326-1: 2012 / EN 61326-2-6: 2012 / EN IEC 63000: 2018
Common Specifications	Not applicable

Montpellier, France
2022/09/12

Claire MALLIÉ
Quality & Regulatory Affairs Junior Director / PRRC

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