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

**(N° dc90132cen)**

## 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 Analyzer** |
| Product name | **Pentra C400 /<br>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.

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 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 61010-1: 2016 / IEC 61010-2-081: 2019 / IEC 61010-2-101: 2018 / IEC 61326-1: 2020 / IEC 61326-2-6: 2020 / UL 61010-1: 2012 / CAN/CSA-C22.2 NO.61010-1-12 (R2022) / CAN/CSA-C22.2 NO.61010.2.081:19 / CAN/CSA-C22.2 NO.61010-1-101:19 / EN IEC 63000: 2018 |
| Common Specifications | Not applicable |

Montpellier, France
2025/04/17

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

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