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EU Declaration of Conformity

(N° dc90153ben)

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 Accessory**
Product name	**Module ISE**
Models	**1280060004**
Basic UDI-DI	**361023ise_pentra_c4008D**
Country of origin	**JAPAN**

Intended Use

The Module ISE is an accessory to clinical chemistry analyzers intended to allow the *in vitro* determination of sodium, potassium and chloride in human plasma, urine and serum by potentiometry using ion selective electrode with associated reference solution, calibrators and controls.
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)*
Common Specifications	Not applicable

Montpellier, France
2022/09/12

Claire MALLIÉ
Quality & Regulatory Affairs Junior Director / PRRC

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