


## EU Declaration of Conformity

(N° dc90146ben)

### WE THE MANUFACTURER

Name	<b>HORIBA ABX SAS</b>
 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	<b>Clinical Chemistry Accessory</b>
Product name	<b>Cuvette Racks PC200</b>
Models	<b>A11A01914</b>
Basic UDI-DI	<b>361023cuvette_rackPM</b>
Country of origin	<b>ITALY</b>

### Intended Use

The cuvette racks comprise *in vitro* diagnostics medical devices disposable cuvettes, destined to be used on HORIBA Medical chemistry analyzers in order to contain samples of biological origin for the clinical chemistry analysis.

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> )
Common Specifications	Not applicable

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Director / PRRC

