

# HORIBA

## **Déclaration de Conformité** **Declaration of Conformity**

(No.dc40041g)

Selon  
According to ISO 17050-1

### **NOUS LE FABRICANT** **WE THE MANUFACTURER**

|                           |                                                                                       |
|---------------------------|---------------------------------------------------------------------------------------|
| Nom<br><i>Name</i>        | <b>HORIBA ABX SAS</b>                                                                 |
| Adresse<br><i>Address</i> | Parc Euromédecine<br>Rue du Caducée<br>BP 7290<br>34184 Montpellier Cedex 4<br>FRANCE |

**ETABLISSEMENTS SOUS NOTRE SEULE RESPONSABILITE LA DECLARATION SUIVANTE ET  
DECLARONS QUE LE PRODUIT  
ESTABLISH UNDER OUR ONLY RESPONSABILITY THE FOLLOWING DECLARATION AND  
DECLARE THAT THE PRODUCT**

|                                                   |                                                                                           |
|---------------------------------------------------|-------------------------------------------------------------------------------------------|
| Catégorie du dispositif<br><i>Device category</i> | <b>Biochemistry reagent</b>                                                               |
| Nom du produit<br><i>Product name</i>             | <b>ABX Pentra CRP CP</b><br>For application on : ABX Pentra 400, Pentra C400, Pentra C200 |
| Modèles<br><i>Models</i>                          | <b>A11A01611</b>                                                                          |
| Pays d'origine<br><i>Country of origin</i>        | Japan                                                                                     |

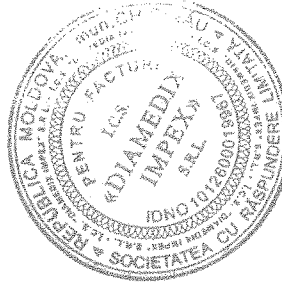
**EST CONFORME AUX DIRECTIVES ET NORMES  
CONFORMS TO DIRECTIVES AND STANDARDS**

|                                 |                                                                                                                                             |
|---------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------|
| Directives<br><i>Directives</i> | 98/79/EC – IVD Medical Devices<br>Classification : Outside Annex II and not for self-testing<br>Conformity Assessment Procedure : Annex III |
| Normes<br><i>Standards</i>      | N/A                                                                                                                                         |

Montpellier, France  
22 octobre 2018  
October 22nd. 2018



**Arnaud PRADEL**  
Vice-Président Exécutif  
Executive Vice President



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