

**HORIBA ABX SAS**

Parc Euromédecine  
Rue du Caducée - BP 7290  
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**Déclaration de Conformité***Declaration of Conformity*

(No.dc20025p)

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 – BP 7290<br>34184 Montpellier cedex 4 - France |

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

|                                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|---------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Catégorie du dispositif<br><i>Device Category</i> | <b>Hematology Reagent</b>                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| Nom du produit<br><i>Product name</i>             | <b>ABX Cleaner 0.5L</b><br>For application on: ABX Micros ES 60, ABX Micros CRP, ABX Micros CRP 200<br><b>ABX Cleaner 1L</b><br>For application on: ABX Pentra 60, ABX Pentra 60 C+, Pentra ES 60, Pentra MS 60, Pentra MS CRP, ABX Pentra 80, ABX Pentra XL 80, Pentra XLR, ABX Pentra 120, ABX Pentra 120 Retic, ABX Pentra DX 120, ABX Pentra DF 120, Pentra DX Nexus, Pentra DF Nexus, Yumizen H500 OT, Yumizen H500 CT, Yumizen H550, Yumizen H1500, Yumizen H2500 |
| Modèle<br><i>Model</i>                            | 0903011<br>0903010                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Pays d'origine<br><i>Country of origin</i>        | France                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |

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

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

Montpellier, France

18 Juin 2018

June 18<sup>th</sup>, 2018**Arnaud Pradel**

Vice Président Exécutif

Executive Vice President

TEMP-4018 Rev.012

HORIBA ABX – Société par Actions Simplifiée 23.859.980 € - RCS Montpellier 328 031 042 – SIRET 328 031 042 000 42 – APE 2651B – N° TVA FR 08328031042