

Déclaration de Conformité Declaration of Conformity

(No.dc20025o)

Selon

According to ISO 17050-1

NOUS LE FABRICANT
WE THE MANUFACTURER

Nom Name	HORIBA ABX SAS
Adresse Address	Parc Euromédecine Rue du Caducée – BP7290 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 Device category	HEMATOLOGY REAGENT
Nom du produit Product name	ABX CLEANER (1L) 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 H1500, Yumizen H2500, Yumizen H550 ABX CLEANER (0.5L) For application on : ABX Micros ES 60, ABX Micros CRP, ABX Micros CRP 200
Modèles Models	0903010, 0903011
Pays d'origine Country of origin	France

EST CONFORME AUX DIRECTIVES ET NORMES
CONFORMS TO DIRECTIVES AND STANDARDS

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

Montpellier, France

06 Juin 2017

June 06th, 2017**Christian DUBUC**

Directeur

Senior Director

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