

HORIBA ABX SAS

Parc Euromédecine
Rue du Caducée - BP 7290
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Déclaration de Conformité UE

EU Declaration of Conformity

(N°DC90141a)

NOUS LE FABRICANT
WE THE MANUFACTURER

Nom <i>Name</i>	HORIBA ABX SAS
 Adresse <i>Address</i>	Parc Euromédecine Rue du Caducée BP 7290 34184 Montpellier Cedex 4 France
Numéro d'enregistrement unique <i>Single Registration Number</i>	FR-MF-000000320

**ETABLISSEMENT SOUS NOTRE SEULE RESPONSABILITE LA DECLARATION
SUIVANTE ET DECLARONS QUE LE PRODUIT**

TAKE SOLE RESPONSIBILITY FOR AND HEREBY DECLARE THAT THE PRODUCT

Catégorie du dispositif <i>Device category</i>	Hematology reagent
Nom du produit <i>Product name</i>	ABX Cleaner 1L ABX Cleaner 0.5L ABX Miniclean 1L
Modèles <i>Models</i>	ABX Cleaner 1L: 0903010 (SAP code: 1210903010) ABX Cleaner 0.5L: 0903011(SAP code: 1210903011) ABX Miniclean 1L: 0403010 (SAP code: 1210403010)
IUD-ID de base <i>Basic UDI-DI</i>	361023cleanerAK
Pays d'origine <i>Country of origin</i>	France
Destination du dispositif <i>Intended Purpose</i>	ABX Cleaner 1L is an enzymatic solution intended for in vitro diagnostic use with proteolytic action for the cleaning of HORIBA Medical blood cell counters. Clinical laboratories use. ABX Cleaner 0,5L is an enzymatic solution intended for in vitro diagnostic use with proteolytic action for the cleaning of HORIBA Medical blood cell counters. Clinical laboratories use.

	ABX Miniclean 1L is an enzymatic solution intended for in vitro diagnostic use with proteolytic action for the cleaning of HORIBA Medical blood cell counters. Clinical laboratories use.
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EST CONFORME AUX DIRECTIVES, REGLEMENTS, NORMES ET SPECIFICATIONS COMMUNES

MEETS THE PROVISIONS OF THE FOLLOWING DIRECTIVES, REGULATIONS, STANDARDS AND COMMON SPECIFICATIONS

Règlements <i>Regulations</i>	Regulation (EU) 2017/746 on in vitro diagnostic medical devices Classe de risques / Risk Class: A ☒ B ☐ C ☐ D ☐
Procédure d'évaluation de la conformité IVDR/ <i>IVDR conformity assessment route</i>	☒ Annex II + ANNEX III + ANNEX IV (Class A devices excluding sterile devices)
Spécifications Communes <i>Common Specifications</i>	Not Applicable

Montpellier, France
25 mai 2022
May 25th, 2022

Claire MALLIÉ
Directrice Junior Qualité & Affaires Réglementaires /PCVRR
Quality & Regulatory Affairs Junior Director/PRRC



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