

HORIBA ABX SAS

Parc Euromédecine

Rue du Caducée - BP 7290

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Déclaration de Conformité UE

EU Declaration of Conformity

(N°dc90119a)

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(S) PRODUIT(S)*****TAKE SOLE RESPONSIBILITY FOR AND HEREBY DECLARE THAT THE
PRODUCT(S)***

Catégorie du dispositif <i>Device category</i>	Hematology reagent
Nom du produit <i>Product name</i>	ABX Diluent 10L ABX Diluent 20L
Modèles <i>Models</i>	0901010 0901020
IUD-ID de base <i>Basic UDI-DI</i>	361023diluentG8
Pays d'origine <i>Country of origin</i>	France
Destination du dispositif <i>Intended Purpose</i>	- ABX Diluent 10L is a buffered isotonic solution intended for in vitro diagnostic use and designed for sheathing and diluting leucocytes (WBC), and for the determination and differentiation of blood cells, and the measurement of hematocrit on HORIBA Medical blood cell counters. Clinical laboratories use. - ABX Diluent 20L is a buffered isotonic solution intended for in vitro diagnostic use and designed for sheathing and diluting leucocytes

(WBC), and for the determination and differentiation of blood cells, and the measurement of hematocrit on HORIBA Medical blood cell counters. Clinical laboratories use.

EST CONFORME AUX DIRECTIVES, REGLEMENTS, NORMES ET SPECIFICATIONS COMMUNES**MEET(S) 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

