

HORIBA ABX SAS

Parc Euromédecine
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Déclaration de Conformité UE

EU Declaration of Conformity

(N°DC90143a)

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 Minipack LMG
Modèles <i>Models</i>	0602050 (SAP code: 1210602050)
IUD-ID de base <i>Basic UDI-DI</i>	361023minipack_img86
Pays d'origine <i>Country of origin</i>	France
Destination du dispositif <i>Intended Purpose</i>	ABX Minipack LMG is constituted of 3 reagents (R1, R2, R3) and a waste container intended for in vitro diagnostic use on HORIBA Medical blood cell counters. ■ R1 is an enzymatic solution with proteolytic action for the cleaning of blood cell counters. ■ R2 is a lysing solution for lysing erythrocytes (RBC) for leucocytes (WBC) counting and differentiation and for hemoglobin determination. ■ R3 is a buffered isotonic solution designed for the determination

	of blood cells counting, WBC differentiation and the measurement of hematocrit. 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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