

HORIBA ABX SAS

Parc Euromédecine

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EU Declaration of Conformity

(N° dc90117ben)

WE THE MANUFACTURER

Name	HORIBA ABX SAS
 Address	Parc Euromédecine Rue du Caducée BP 7290 34184 Montpellier Cedex 4 FRANCE
Single Registration Number	FR-MF-000000320

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

Device category	Hematology Reagent
Product name	ABX Alphalyse 0.4L / ABX Alphalyse 360 mL
Models	0906004 / 0906014
Basic UDI-DI	361023lyseX2
Country of origin	FRANCE

Intended Use

ABX Alphalyse 0.4L / ABX Alphalyse 360 mL is a lysing solution intended for *in vitro* diagnostic use and designed for lysing erythrocytes (RBC) for leucocytes (WBC) counting and differentiation and for hemoglobin determination on HORIBA Medical blood cell counters.

Clinical laboratories use.

MEET(S) THE PROVISIONS OF THE FOLLOWING DIRECTIVES, REGULATIONS, STANDARDS AND COMMON SPECIFICATIONS

Regulations	Regulation (EU) 2017/746 on <i>in vitro</i> diagnostic medical devices Risk Class: A ☒ B ☐ C ☐ D ☐
IVDR conformity assessment route	☒ ANNEX II + ANNEX III + ANNEX IV (<i>Class A devices excluding sterile devices</i>)
Common Specifications	Not applicable

Montpellier, France
2022/09/12

Claire MALLIÉ
Quality & Regulatory Affairs Junior
Director / PRRC