HORIBA ABX SAS
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Rue du Caducée - BP 7290
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EU Declaration of Conformity

(N° dc90122ben)

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 Eosinofix 1L**
Models	**0206010**
Basic UDI-DI	**361023eosinofix3H**
Country of origin	**FRANCE**

Intended Use

ABX Eosinofix 1L is a lysing solution intended for *in vitro* diagnostic use and designed for lysing erythrocytes (RBC) for leucocytes (WBC) counting and differentiation on HORIBA Medical blood cell counters.
Clinical laboratories use.

HORIBA Medical

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

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

Montpellier, France
2022/09/12

Claire MALLIÉ
Quality & Regulatory Affairs Junior Director / PRRC

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