

**HORIBA ABX SAS**

Parc Euromédecine

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# EU Declaration of Conformity

(N° dc90125ben)

**WE THE MANUFACTURER**

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

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

|                   |                            |
|-------------------|----------------------------|
| Device category   | <b>Hematology Reagent</b>  |
| Product name      | <b>ABX Minilyse LMG 1L</b> |
| Models            | <b>0702010</b>             |
| Basic UDI-DI      | <b>361023lyseX2</b>        |
| Country of origin | <b>FRANCE</b>              |

**Intended Use**

**ABX Minilyse LMG 1L** 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<br><b>Risk Class:</b> A <input checked="" type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D <input type="checkbox"/> |
| IVDR conformity assessment route | <input checked="" type="checkbox"/> 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