HORIBA ABX SAS
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EU Declaration of Conformity

(N° dc90143ben)

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 Minipack LMG**
Models	**0602050**
Basic UDI-DI	**361023minipack_lmg86**
Country of origin	**FRANCE**

Intended Use

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.

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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