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EU Declaration of Conformity

(N° dc90009ben)

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 Quality Control**
Product name	**ABX Minotrol 16 (L), ABX Minotrol 16 (N), ABX Minotrol 16 (H), ABX Minotrol 16 (2xL), ABX Minotrol 16 (2xN), ABX Minotrol 16 (2xH)**
Models	**1300135996, 1300135997, 1300135999, 2042208, 2042202, 2042209**
Basic UDI-DI	**361023minotrol16BH**
Country of origin	**USA**

Intended Use

ABX Minotrol 16 is a tri-level control intended for *in vitro* diagnostic use and designed for use in monitoring the accuracy and precision of HORIBA hematology blood cell counters for the following parameters in clinical laboratories (except for Micros Care ST): WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, PLT, MPV, LYM#, LYM%, MON#, MON%, GRA#, GRA%.
Parameters can be different according to the instrument, please refer to the assay value data sheet for specific instrument models.

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 IX (Chap I & III, chap II section 4) + ANNEX IV *(Class B & C devices excluding self-testing and near patient testing devices)*	EU CERTIFICATE #: IVDR 745367 Name of Notified Body: BSI Group The Netherlands B.V Notified Body Identification: 2797
Common Specifications	Not applicable	

Montpellier, France
2025/07/23

Claire MALLIÉ
Quality & Regulatory Affairs Junior Director / PRRC

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