


EU Declaration of Conformity

(N° dc90004ben)

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 Difftrol (L), ABX Difftrol (N), ABX Difftrol (H), ABX Difftrol (2L), ABX Difftrol (2N), ABX Difftrol (2H)
Models	1300136011, 1300136015, 1300136019, 2062207, 2062203, 2062208
Basic UDI-DI	361023difftrolXR
Country of origin	USA

Intended Use

ABX Difftrol is a tri-level multiparameter 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: WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW-CV, RDW-SD, PLT, PLT-Ox, MPV, NEU%, NEU#, LYM%, LYM#, MON%, MON#, EOS%, EOS#, BAS%, BAS#, IMG%, IMG#, NRBC%, NRBC#, TNC, LPF. 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 <i>in vitro</i> diagnostic medical devices Risk Class: A <input type="checkbox"/> B <input checked="" type="checkbox"/> C <input type="checkbox"/> D <input type="checkbox"/>	
IVDR conformity assessment route	<input checked="" type="checkbox"/> ANNEX IX (Chap I & III, chap II section 4) + ANNEX IV (<i>Class B & C devices excluding self-testing and near patient testing devices</i>)	EU CERTIFICATE #: IVDR 745367 Name of Notified Body: BSI Group The Netherlands B.V Notified Body Identification: 2797
Common Specifications	Not applicable	

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