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EU Declaration of Conformity

(N° dc90014ben)

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 Analyzer**
Product name	**ABX Pentra XL 80**
Basic UDI-DI	**361023pentra_xl80LB**
Country of origin	**FRANCE**

Intended Use

The ABX Pentra XL 80 is a quantitative multi-parameters fully automated hematology analyzer used for *in vitro* diagnostic testing of anticoagulated whole blood specimens.
It is used for screening a physiological state (quantitative or qualitative hematology abnormality detection) or a pathological state of patient populations found in clinical laboratories.
The ABX Pentra XL 80 classifies and enumerates the following parameters:
WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW-CV, RDW-SD, PLT, PDW, PCT, MPV, LYM#, LYM%, MON#, MON%, NEU#, NEU%, EOS#, EOS%, BAS#, BAS%, ALY#, ALY%, LIC#, LIC%.

HORIBA

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
Directives	2011/65/EU - Amended by 2015/863/EU - ROHS Directive Category: 8- Medical Devices	
Standards	IEC 61010-1: 2010 / IEC 61010-2-081: 2019 / IEC 61010-2-101: 2018 / EN 61326-1: 2020 / EN 61326-2-6: 2020	
Common Specifications	Not applicable	

Montpellier, France
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Claire MALLIÉ
Quality & Regulatory Affairs Junior Director / PRRC