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EU Declaration of Conformity

(N° dc90015ben)

WE THE MANUFACTURER

Name	HORIBA ABX SAS
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Single Registration Number	FR-MF-000000320

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

Device category	Hematology Analyzer
Product name	Pentra XLR
Basic UDI-DI	361023pentra_xlrEA
Country of origin	FRANCE

Intended Use

The Pentra XLR 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 Pentra XLR 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%, RET#, RET%, RETL, RETM, RETH, CRC, MRV, IRF, RHCc.

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 ☐ B ☒ C ☐ D ☐	
IVDR conformity assessment route	☒ 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
Directives	2011/65/EU - RoHS Restriction of Hazardous Substances (Classification: Category 8 Medical Device)	
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	

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