HORIBA ABX SAS
Parc Euromédecine
Rue du Caducée - BP 7290
34184 Montpellier Cedex 4 - FRANCE
Phone: +33 (0)4 67 14 15 16
Web: www.horiba.com

EU Declaration of Conformity

(N° dc90051ben)

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	**Clinical Chemistry Calibrator**
Product name	**ABX Pentra CRP Cal**
Models	**A11A01616**
Basic UDI-DI	**361023pentra_crp_calMN**
Country of origin	**JAPAN**

Intended Use

ABX Pentra CRP Cal is used for calibration of *in vitro* diagnostic quantitative HORIBA methods with the following parameter(s):
C-Reactive Protein (CRP)
Clinical laboratories use.

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
Common Specifications	Not applicable	

Montpellier, France
2025/05/30

Claire MALLIÉ
Quality & Regulatory Affairs Junior Director / PRRC

TEMP-5695 Rev.005