HORIBA ABX SAS
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EU Declaration of Conformity

(N° dc90178aen)

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 CRP Trol I / ABX CRP Trol III**
Models	**3201054580 / 3201054581**
Basic UDI-DI	**361023crp_trol62**
Country of origin	**JAPAN**

Intended Use

The **ABX CRP Trol I** is a serum of C-reactive protein intended for *in vitro* diagnostic use and designed for use in monitoring the accuracy and precision of HORIBA hematology blood cell counters with C-reactive protein parameter measurement by immuno-turbidimetry technique in clinical laboratories.
The **ABX CRP Trol III** is a serum of C-reactive protein intended for *in vitro* diagnostic use and designed for use in monitoring the accuracy and precision of HORIBA hematology blood cell counters with C-reactive protein parameter measurement by immuno-turbidimetry technique in clinical laboratories.

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
2025/12/16

Claire MALLIÉ
Quality & Regulatory Affairs Junior Director / PRRC

TEMP-5695 Rev.005