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SIEMENS Healthineers

EU Declaration of Conformity

for INNOVANCE PFA-200 System

Siemens Healthcare Diagnostics Products GmbH hereby declares conformity to REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU and DIRECTIVE 2011/065/EU for the following In Vitro Diagnostic Device:

Product Name

INNOVANCE PFA-200 System

Intended Purpose Statement of Device

The intended use of the INNOVANCE PFA-200 System is to aid in the detection of platelet dysfunction in citrated human whole blood. The system is for in vitro diagnostic use only.
The semi-automated system is comprised of an analyzer and test cartridge system in which the process of platelet adhesion and aggregation following a vascular injury is simulated in vitro. Platelet dysfunction detected by the system may be acquired, inherited, or induced by platelet inhibiting agents. The system determines the time from the start of the test until the platelet plug occludes the aperture, and reports that time interval as the closure time (CT). The CT is an indicator of platelet function in the analyzed whole blood sample.

Catalogue Number (REF)	Siemens Material Number (SMN)	Package Size / Description
B4170-100	10488536	Stand Alone instrument

Basic UDI-DI (Basic Unique Device Identification)

0405686900872W4

Risk classification according to the rules of Annex VIII REGULATION (EU) 2017/746

Class A

Manufacturer and address of registered place of business

Manufacturer	Siemens Healthcare Diagnostics Products GmbH
Single Registration Number	DE-MF-000005039
Address	Emil-von-Behring-Str. 76 35041 Marburg Germany

Notified Body

Name	N/A
Identification Number	N/A
Address	N/A

Conformity Assessment Procedure	Article 48 (10)

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Notified Body Certificate Number

N/A

Common Specifications the product conforms with

Identifier	Title of Document
N/A	N/A

This declaration of conformity is issued under the sole responsibility of Siemens Healthcare Diagnostics Products GmbH according to REGULATION (EU) 2017/746 and DIRECTIVE 2011/065/EU for the following In Vitro Diagnostic Device and any other Union legislation as stated in the Conformity with Standards and supersedes any declaration issued previously for the same product.

Signature: *Electronically signed by: Christian Hainer*
Reason: I am approving this document
Date: Dec 17. 2025 11:32:26 GMT+1

Email: CHRISTIAN.HAINER@SIEMENS-HEALTHINEERS.COM

Christian Hainer
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Siemens Healthcare Diagnostics Products GmbH
Marburg, Germany

Date Dec 17, 2025