SIEMENS

EU Declaration of Conformity

PHẠM THỊ THU HÀ
Digitally signed by PHẠM THỊ THU HÀ
Date: 2020.12.02 17:49:04 +07'00'

CE

We hereby declare that the products described below conform to all applicable requirements of Council Directive 98/79/EC for in vitro diagnostic medical devices.

Legal Manufacturer:	Siemens Healthcare Diagnostics Inc. 511 Benedict Avenue Tarrytown, NY, 10591, USA
Place of Manufacture:	Fisher Diagnostics A division of Fisher Scientific Company, LLC A part of Thermo Fisher Scientific, Inc. 8365 Valley Pike Middletown, VA, 22645, USA
EU Authorized Representative:	Siemens Healthcare Diagnostics Manufacturing Ltd. Chapel Lane Swords, Co. Dublin, Ireland
Product Names:	See *List of Products*
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Identifier:	DoC_ADVIA 2120 and 2120i Wash Reagents
Version:	2.0

This declaration of conformity is issued under the sole responsibility of Siemens Healthcare Diagnostics Inc.
This declaration supersedes any declaration issued previously for the same product.

Signature: Marinelli Rose

Digitally signed by Marinelli Rose
DN: serialNumber=Z00271HB, givenName=Rose, sn=Marinelli, o=Siemens, cn=Marinelli Rose
Reason: I am approving this document
Date: 2020.06.05 15:05:51 -04'00'

Rose Marinelli
Regulatory Professional 5
Siemens Healthcare Diagnostics Inc.
Tarrytown, NY USA

Date
[YYYY-MM-DD]

EU DECLARATION OF CONFORMITY

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List of Products

Product Name	Catalogue Number (REF)	Siemens Material Number (SMN)	Legacy Product Code
ADVIA 2120 and 2120i RBC Flow Cell Wash		10734561	
ADVIA 2120 and 2120i Perox Flow Cell Wash		11306489	
ADVIA 2120 and 2120i Aspiration Pathway Wash		11306490	
ADVIA 2120 and 2120i Vent Line Wash		11306492	

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THIS SECTION IS NOT TO BE DISTRIBUTED EXTERNALLY WITH THE DECLARATION OF CONFORMITY (RESTRICTED – FOR DOCUMENTATION PURPOSES)

Revision History

Version Number	Date of Version [YYYY-MM-DD]	Author of Version	Description of Changes