

EU Declaration of Conformity

Basic UDI-DI: 038074ARP0174PC
Basic UDI-DI Name: Folate
Risk Class: Class B

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
1P74-25 1P74-35	ARCHITECT Folate Reagent Kit	60982	W0102070103
1P74-40	ARCHITECT Folate RBC Lysis Diluent	54455	W01029003
1P74-50	ARCHITECT Folate Manual Diluent	58237	W01029003
1P74-01	ARCHITECT Folate Calibrators	41931	W0102152206
1P74-10	ARCHITECT Folate Controls	41932	W0102152006
3P21-60	Folate Lysis Reagent	54455	W01029003

Manufacturer (Name and Address)	Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford Ireland	
Manufacturer SRN	IE-MF-000010070	
Authorized Representative (Name and Address)	N/A	
Authorized Representative SRN	N/A	
Produced by (Site of Manufacture) (Name and Address)	Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford Ireland	
Notified Body (Name and Identification Number)	TÜV Süd Product Service GmbH, Certification Body, Ridlerstraße 65, 80339 Munich, Germany Notified Body Number 0123	
Conformity Assessment Procedure	Quality Management System Annex IX Chapters I and III, Including an assessment of the technical documentation for devices concerned on the basis of representative samples	EU Certificate No. No. V12 054869 0013
Common Specifications (CS)	N/A	

We, the undersigned, hereby declare that the in vitro diagnostic medical device(s) described above conform with the applicable provisions of the Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on In Vitro Diagnostic Medical Devices. This declaration is made in accordance with Annex IV of the IVD Regulation and is issued under the sole responsibility of the manufacturer.

Full Name: David Spellman

Function: Director Quality Assurance/Site Quality Head

Signature: 

Date of Approval: 23 JAN 2024

Full Name: Sandra Gallagher

Function: Manager Regulatory Affairs

Signature: 

Date of Approval: 19-JAN-2024

Signed for, and on

behalf of: Abbott Ireland Diagnostics Division Lisnamuck, Longford, Co. Longford Ireland

Date Issued: 23 JAN 2024

Supersedes: 30 Nov 2022

Place Issued: Lisnamuck, Longford, Co. Longford, Ireland

Effective (Date or Lot Number): 23 JAN 2024