



EU Declaration of Conformity

Basic UDI-DI: 038074AIP0748LL
Basic UDI-DI Name: Alinity i TSH
Risk Class: Class B

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
07P4820 07P4830	Alinity i TSH Reagent Kit	54386	W01020410
07P4801	Alinity i TSH Calibrators	38272	W01020410
07P4810	Alinity i TSH Controls	38271	W01020410

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,	EU Certificate No. No. V12 054869 0013	
	Including an assessment of the technical documentation for devices concerned on the basis of representative samples		
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: 30 Aug 2022

Signed for, and on behalf of: Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford Ireland

Date Issued: 30 Aug 2022

Supersedes: N/A

Full Name: Sandra Gallagher

Function: Manager Regulatory Affairs

Signature:

Date of Approval: 19-AUG-2022

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

Effective (Date or Lot Number): All lots manufactured with IFU commodity G71292R03 or higher.