



Abbott Molecular Inc.
1300 East Touhy Avenue
Des Plaines Illinois 60018
United States of America
224-361-7000

Declaration of Conformity

Basic UDI-DI: 0884999VyN0887TD

Risk Class: Class A, Rule 5(a)

List Number(s) of Device	Name(s) and Description(s) of Device	GMDN Code	EMDN Code
08N87-010	Vysis IntelliFISH Hybridization Buffer	60120	W01030799
08N87-015	Vysis IntelliFISH Hybridization Buffer	60120	W01030799
Intended Purpose: The Vysis IntelliFISH Hybridization Buffer is used with fluorescence in situ hybridization (FISH) probes to facilitate hybridization of the probes to their genomic targets within the specimen.			

Legal Manufacturer Name	Abbott Molecular Inc.
Legal Manufacturer Single Registration Number	US-MF-000017776
Legal Manufacturer Address	1300 E. Touhy Ave. Des Plaines, IL USA 60018
Authorized Representative Name in Europe	Abbott GmbH
Authorized Representative Single Registration Number	DE-AR-000009457
Authorized Representative Address	Max-Planck-Ring 2 65205 Wiesbaden, Germany
Technical Documentation Owner	Abbott Molecular Inc.
Technical Documentation Owner Address	1300 E. Touhy Ave. Des Plaines, IL USA 60018
Conformity Assessment Procedure	Annex II and III

I, the undersigned, hereby declare that the *in vitro* diagnostic medical device(s) described above and bearing the CE-Marking, conform with the applicable provisions of the IVD Regulation 2017/746 of the European Parliament and of the Council. This EU Declaration of Conformity is issued under the sole responsibility of Abbott Molecular Inc.

Signature:



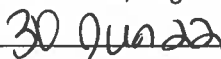
Full Name (printed):

Kathy Wessberg

Position:

Divisional Vice President, Regulatory and Medical Affairs

Date Issued:



Place Issued:

Abbott Molecular Inc. Des Plaines, IL USA 60018

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