



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

Declaration of Conformity

IVDD Category:**Self-Declared**

Legal Manufacturer's Name:
Legal Manufacturer's Address:

Abbott Molecular Inc.
1300 E. Touhy Ave.
Des Plaines, IL USA 60018

Name of Authorized Representative in Europe:
Address of Authorized Representative in Europe:

Abbott GmbH
Max-Planck-Ring 2
65205 Wiesbaden- Germany

List Number(s) of Device	GMDN Code	Classification	Name(s) of Device
01N36-020	60084	Self-Declared	Vysis LSI PML/RARA Dual Color, Dual Fusion Translocation Probe Set

Name of technical documentation owner
Address of technical documentation owner

Abbott Molecular Inc.
1300 E. Touhy Ave.
Des Plaines, IL USA 60018

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 *Medizinproduktegesetz (Medical Devices Act, Germany)* transposing EC Directive 98/79/EC concerning *in vitro* diagnostic medical devices.

This declaration of conformity is issued under the sole responsibility of the manufacturer. This declaration is made in accordance with Annex III of the IVD Directive 98/79/EC and harmonized standards listed in the List of Standards chapter.

Signature:



Full Name (printed):

Kathy Wessberg

Position:

Divisional Vice President, Regulatory and Medical Affairs

Date:

25 May 22

Place:

Abbott Molecular Inc. Des Plaines IL USA 60018