



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
04N61-020	61638	Self-Declared	Vysis CDKN2A/CEP 9 FISH Probe Kit

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):

Stacy Ferguson

Position:

Director, Regulatory Affairs

Date:

25-May-2022

Place:

Abbott Molecular Inc. Des Plaines IL USA 60018

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