



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
05N56-020	61464	Self-Declared	Vysis TP53/CEP 17 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:

Place:

Abbott Molecular Inc. Des Plaines IL USA 60018

**End of Document**