



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

Declaration of Conformity

IVDD Category:

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

Self-Declared

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 |
|--------------------------|-----------|----------------|---------------------------------------|
| 04N09-020 | 62955 | Self-Declared | Vysis ETV6 Break Apart 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):

Kathy Wessberg

Position:

Divisional Vice President, Regulatory and Medical Affairs

Date:

25 May 22

Place:

Abbott Molecular Inc. Des Plaines IL USA 60018

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