

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
D-65205
Wiesbaden- Germany

List Number(s) of Device	GMDN Code	Classification	Name(s) and Description(s) of Device
04N02-022	61464	Self-Declared	Vysis CLL 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

ISO 13485:2016 Certificate No. 11873023.PDWS issued by Underwriters Laboratories (UL) to Abbott Molecular, with an effective Date of December 16, 2017 and an Expiry Date of December 15, 2020.

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 is made in accordance with Annex III of the IVD Directive 98/79/EC. The relevant harmonised standards used or referenced are as follows:

- ISO 13485 Medical devices – quality management systems – requirements for regulatory purposes under Medical Device Single Audit Program (MDSAP)
- ISO 14971 Medical devices – application of risk management to medical devices.
- EN 13641 Elimination or reduction of risk of infection related to *in vitro* diagnostic reagents.
- ISO 23640 *In vitro* diagnostic medical devices - Evaluation of stability of *in vitro* diagnostic reagents.
- EN 13612 Performance evaluation of *in vitro* diagnostic medical devices.
- ISO 18113-1 *In vitro* diagnostic medical devices- Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions, and general requirements
- ISO 18113-2 *In vitro* diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: *In vitro* diagnostic reagents for professional use.

- ISO 18113-3 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 3: In vitro diagnostic instruments for professional use.
- ISO 15223-1 Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied.
- 91/155/EEC COMMISSION DIRECTIVE of 5 March 1991 defining and laying down the detailed arrangements for the system of specific information relating to dangerous preparations in implementation of Article 10 of Directive 88/379/EEC ("Safety Data Sheets")
- 80/181/EEC Council Directive of 20 December 1979 on the approximation of the laws of the Member States relating to units of measurement and on the repeal of Directive 71/354/EEC.
- 1272/2008/EC Regulation No. 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling, and packaging of substances and mixtures and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.
- 1907/2006 EC as amended Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.

Signature:



Full Name (printed):

Kathy Wessberg

Position:

Senior Director Regulatory Affairs

Date:

October 15, 2020

Place:

Abbott Molecular Inc., Des Plaines, IL USA 60018

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