

## Declaration of Conformity (DOC) Corrigendum

Product name: Fluorescence in situ hybridization (FISH) probes

EDMA Code: 16-02-01-90-00 OTHER ACQUIRED GENE OR CHROMOSOME ALTERATION TESTS

Class: Other device not listed under Annex II IVDD and not for self-testing

Date of the DOC: 2022-05-20

Classification according to IVDR: Class C

This corrigendum intends to correct the following information in DoC(s) of the above listed product(s).

Change in manufacturer address from (1000 Youngs Road, Suite 207, Williamsville, NY 14221, USA) to (3370 Walden Avenue, Suite 114, Depew, NY 14043, USA).

According to Regulation (EU) 2017/746 (IVDR), for legacy devices according to Art. 110 (3), amended by Regulation (EU) 2022/112, Art. 1, no changes to DOCs signed prior to May 26, 2022, can be performed. In case of the above-described non-significant change(s) (as defined in MDCG 2022-6), the existing DOC(s) is (are) still valid and this Corrigendum will be attached to the originally signed DOC(s). The DOC(s) will be updated upon transition to IVDR.

Depew  
Place/Date

12/11/2023

  
legally binding signature

Michael Bianchi  
Director of Operations and Development  
Name and function