CE

EC Declaration of Conformity

in accordance with Directive 98/79/EC

Manufacturer: Amoy Diagnostics Co., Ltd.
39 Dingshan Road, Haicang District,
Xiamen, Fujian 361027, PR China

Product: AmoyDx® *EML4-ALK* Fusion Gene Detection Kit

Model: 24 tests/kit

Category: 98/79/EC Others

Conformity assessment route: Self-declaration

Applicable Standards:

- EN ISO 13485
  Medical devices – Quality management systems – Requirements for regulatory purposes
- EN ISO 14971
  Medical devices – Application of risk management to medical devices
- EN ISO 980
  Graphical symbols for use in the labelling of medical devices
- EN 13612
  Performance evaluation of in vitro diagnostic medical devices
- EN 13640
  Stability testing of in vitro diagnostic reagents
- EN ISO 18113
  In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling)

We, the Manufacturer, herewith declare with sole responsibility that our product mentioned above meets the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.

We hereby explicitly appoint Wellkang Ltd t/a Wellkang Tech Consulting located at 29 Harley Street, London W1G 9QR, UK to act as our European Authorised Representative as defined in the aforementioned Directive.

Signed on 29 /(Day) June /(Month) of 2015. Place Xiamen .

Represented by

Signature Huiying Le

Name of authorized signatory: Huiying Le

Position held in the company: QA/QC Manager

Seal/Stamp: AMOY DIAGNOSTICS CO., LTD 厦门艾德生物医药科技股份有限公司 3502056616742

AmoyDx