



**Announcement of China Food and Drug Administration on Issuing
the Appendix: In Vitro Diagnostic Reagents to the Measures for the
Production Quality Management of Medical Devices
(No. 103 in 2015)**

Released on July 10, 2015

To reinforce the supervision and administration of medical device production, and standardize the production quality management of medical devices, the China Food and Drug Administration has organized the drafting of the *Appendix: In Vitro Diagnostic Reagents to the Measures for the Production Quality Management of Medical Devices* in accordance with the *Regulation on the Supervision and Administration of Medical Devices* (Decree No. 650 of the State Council) and *Measures for the Supervision and Administration of Medical Device Production* (Decree No. 7 of the China Food and Drug Administration), and hereby issued it.

This Appendix describes the special requirements for the production quality management of in vitro diagnostic reagents. The production quality management system for in vitro diagnostic reagents shall comply with the requirements of the *Measures for the Production Quality Management of Medical Devices* and this Appendix.

Hereby it is announced.

Attachment: *Appendix: In Vitro Diagnostic Reagents to the Measures for the Production Quality Management of Medical Devices*

China Food and Drug Administration

Attachment

Appendix: In Vitro Diagnostic Reagents to the Measures for the Production Quality Management of Medical Devices

Part I Scope and Principles

1.1 This Appendix is applicable to the in vitro diagnostic reagents subject to the administration of medical devices.

1.2 This Appendix describes the special requirements for the production quality management of in vitro diagnostic reagents.

Part II Special Requirements

2.1 Personnel

2.1.1 The production, technical and quality management personnel of in vitro diagnostic reagents shall have the professional knowledge related to the products, e.g. medicine, medical laboratory science, biology, immunology or pharmaceuticals, as well as the corresponding practical experience to ensure their ability for performance of own duties in the production and quality management.

2.1.2 The staffs working in clean room (area) shall be periodically trained with regard to the basic knowledge about sanitation and microbiology as well as the cleaning activities. Any staff entering the clean room (area) temporarily shall be guided and supervised.

2.1.3 All staffs engaging in the production of in vitro diagnostic reagents, including cleaning, repair and other personnel, shall receive the professional and safety protection trainings on the basis of the products involved and the production activities they take part in.

2.1.4 The requirements for cleaning of staffs shall be prepared, while the rules for sanitation of staffs working in clean room (area) shall be developed. To enter clean room (area), staffs shall be cleaned according to a certain procedure, and wear work cap, mask, clean work uniform, and work shoes. Any operator touching product with bare hands shall disinfect hands in a certain interval. The disinfectants for bare hands shall be replaced periodically.

2.1.5 The requirements for staff health shall be defined, while staff health records shall be created. Operators in direct contact with materials and products shall receive physical examination at least once a year. Any staff with contagious and infectious diseases shall not undertake the work in direct contact with product.

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