Application standards

Device: SARS-CoV-2 IgG/IgM Rapid Test

Manufacturer: Zhuhai Encode Medical Engineering Co., Ltd

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1 Applicable standards

1.1 Product quality management system

The quality management system in the production process is established according to ISO 13485-2016 medical device quality management system to ensure the stability and conformity of product quality.

1.2 Product labels and instructions

Information and sign contained in the product label、instructions accordance with EN ISO 15223-1:2016、EN ISO 18113-1、Annex Ⅰ B 8.

1.3 Performance Evaluation

Product performance is assessed in accordance with EN 13612:2002 to ensure safety and accuracy during use.

1.4 Product stability study

Product stability during transportation, storage and use is evaluated in accordance with the requirements of the EN ISO 23640:2015 standard.

1.5 Risk management

Conduct research on the risk management of products in the process of production and use in accordance with the requirements of ISO 14971:2012 standard, and control the risks within an acceptable range to ensure that the benefits of products exceed the risks.

1.6 Vigilance System

Set up the product quality alert system in strict accordance with the requirements of MEDDEV 2.12/1 RAV8 to ensure the company's contact with relevant organizations and institutions to solve the product quality problems in the first time.

2 List of standard

Table 1 List of standard

NO	Standard code	Standard
1	EN ISO 14971:2012	《Medical device –Application of risk management to medical devices 》

2	EN ISO 23640：2015	《Evaluation of stability of in vitro diagnostic reagents》
3	EN 13612：2002	《Performance evaluation of in vitro diagnostic medical devices 》
4	EN ISO 15223-1:2016	《Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied 》
5	EN ISO 18113-1-1/-2/-3	《In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling)》
6	ISO 13485-2016	《Medical devices - Quality management systems 》
7	MEDDEV 2.12/1 rev8	《Vigilance System》