

CE Product list

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

Manufacturer Zhuhai Encode Medical Engineering Co., Ltd

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1 Product name, model and classification

The EDMS code of SARS-CoV-2 IgG/IgM Rapid Test (Colloidal Gold) is 15.04.80.90

Product packaging specifications are 1 person/box, 3 people/box, 5 people/box, 10 people/box, 20 people/box, 25 people/box, 40 people/box, 50 people/box.

2 Product classification and rules

2.1 Product classification

In accordance with the 98/79/EC, SARS-CoV-2 IgG/IgM Rapid Test (Colloidal Gold) is in vitro diagnostic reagent.

2.2 Classification rules

According to 98/79 / EC appendix II classification principles of medical equipment products, SARS-CoV-2 IgG/IgM Rapid Test (Colloidal Gold) belong to others.

3 Product certification route

SARS-CoV-2 IgG/IgM Rapid Test was conducted using 98/79/EC Annex III