Urgent security information

Recall

concerning

2019-nCoV Ag Saliva Rapid Test Card
(Immunochromatography)

Guangzhou Decheng Biotechnology Co; LTD

23.04.2021

sender:

Guangzhou Decheng Biotechnology Co., LTD
Room 218, Building 2, No 68, Nanxiang Road, Science City
Huangpu District, 510000, Guangzhou, P.R. China

addresse:

Users, Patients, Specialist Dealers

Identification of the affected medical devices:

2019-nCoV Ag Saliva Rapid Test Card
(Immunochromatography)

Affected batch numbers:

05821002C
05821003C

Description of the problem, including the cause identified:

The above product has been delivered in a repackaging which does not comply with the applicable guidelines with incorrect information on primary packaging, secondary packaging and instructions for use:

Incorrect components are indicated on the label of the box. Here testcassette, saliva takers, dripper and tube are mentioned. However, these are not used for this test according to the instructions for use. Regardless, the German translation has not been optimally successful.

In addition to the manufacturer and the EC Rep, the label of the outer packaging also mentions the subsidiary in the USA. This is not provided for in the law and is confusing in terms of responsibilities.

The Salivia Swab label does not include a CE marking. Furthermore, no EU representative is mentioned.

Leaflet:
Sample requirement 3.: This requirement should be mentioned first. Furthermore, the requirement that no food or drink be used 2 hours before the test is contrary to the requirements in the short manual and the packaging. There, 30 minutes are specified.
The Quick Start Guide does not include the CE marking and designation of the EU representative.

These are flagging errors that can cause the test to be applied incorrectly and thus *display both false* positive *and false* negative results.
It cannot be ruled out *that tested persons in a false negative* test, themselves *users or third parties* will endanger or endanger themselves.
When applying with a negative test result, we recommend a recoverytest with a compliant test and an extended *risk assessment on the* extent *of contact with* third parties.

What measures should be taken by the addressee?

All tests *in your possession* must be blocked immediately and returned in such a way that re-use is excluded.

Please let us know immediately how many tests you still have in your possession and how many tests *you have passed on to* which recipients (name address, contact details).

To return the products, please contact the above-mentioned EU representative to clarify the return instructions.

The recall should be completed by 03.05.2021.

Disclosure of the information described here:

Please ensure in your organization that all users of the above-ced products and other persons to be informed are aware of this **urgent safety information.** If you have handed over the products to third parties, please forward a copy of this information or inform the contact person provided below.

Please keep this information at least until the action has been completed.

The Federal Institute for Medicinal Products and Medical Devices has received a copy of this "Urgent Safety Information".

contact:

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