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Ministry of Public Health,
Welfare and Sport

Lotus NL B.V.

Koningin Julianaplein 10,

1e Verd, 2595AA,

The Hague, Netherlands.

Digitally signed by Perminov Andrei
Date: 2023.08.03 10:24:08 EEST
Reason: MoldSign Signature
Location: Moldova

Date: 24 March 2020

Subject: Notification in vitro diagnostics

Dear Mr. Wei,

On March 18, 2020 we received your notification according to article 4 in-vitro diagnostics, under the name Xiamen Boson Biotech Co., Ltd., with the European Representative Lotus NL B.V., put out into the European market the below mentioned products.

This product has been registered as an in-vitro diagnostic with the number:

2019-nCoV IgG/IgM Combo Test, Chikungunya IgG/IgM Combo Test, Zika Virus IgG/IgM Combo Test, K2 Test, Methylphenidate Test, Methaqualone Test, Adenovirus Antigen Test, S.typhi/paratyphi Antigen Duo Test, Dengue NSI Antigen Test, Influenza A Test
(geen merknaam) (NL-CA002-2020-49745)
Amphetamine Test, Benzodiazepine Test, Cocaine Test, Methamphetamine Test, T HC Test, Opiate Test, Methadone Test, Drugs of Abuse Test Cup,Drugs of Abuse Panel Test, Fecal Occult Blood Test, Adeno/Rota Virus Antigen Combo Test, Influenza A +B Test, Strep A Test
(geen merknaam) (NL-CA002-2020-49746)

Herewith you will have fulfilled your obligations under Article 4.

For future correspondence concerning the above-mentioned product we kindly request you to use this number. No rights can be derived from this number; its sole purpose is to simplify the administrative side of the notification.

The registration of the above product as a medical device APPLICABLE PRODUCTS according to the requirements with the European Directive 98/79/EC is subject to possible revisions of the European law concerning the classification of medical devices and to advanced scientific understanding (see art. 10 of the European Directive 98/79/EC).

Notification of medical devices implies that Xiamen Boson Biotech Co., Ltd., has applied the CE conformity marking on the corresponding product before bringing it out into the

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EU-member state market. Consequently, Lotus NL B.V. guarantees that the medical device meets the essential requirements as stated in the Guideline and the Decision.

To complete this, we would like to point out that a medical device must comply with the demands of the Decision Medical Devices. This Decision is based upon in-vitro diagnostics 98/79/EC and the legal text requirements for The Netherlands. We especially would like to point out the language requirement as required in The Netherlands, the requirements for keeping at our disposal the technical documentation and the obligation to having a Post Marketing Surveillance and vigilance system.

Finally, I note that with your notification - the administrative notification as manufacturer - and this letter there is no judgment on an opinion on the status or classification of the in vitro diagnostic product for the purposes of this Law and regulations. Where appropriate, IGZ, responsible for monitoring the compliance by or pursuant to the law, can take a position on the status of a product which, according to settled case law ultimately for the national court to determine whether a product falls within the definition of an in vitro diagnostic product.

The Minister for Health and Sport,

on behalf of this,

Head of Pharmaceuticals

Sir. M.J. van de Velde