CIBG
Ministry of Public Health, Welfare and Sport

Lotus NL B.V.

Koningin Julianaplein 10,

1e Verd, 2595AA,

The Hague, Netherlands.

Date: 13 August 2020

Subject: Notification in vitro diagnostics

Dear Mr. Wei,

On August 9, 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:

D-Dimer Test, H.Pylori Antigen Test, H.Pylori Antibody Test, Rotavirus Antigen Test, V.Cholerae O1/O139 Duo Test, Salmonella typhi Antigen Test, Salmonella typhi IgG/IgM Combo Test, Rickettsia IgG/IgM Combo Test, Tuberculosis Test,Cardiac Panel Test

(geen merknaam) (NL-CA002-2020-52870)

Rapid SARS-CoV-2 Antigen Test Card, Syphilis Antibody Test, Malaria Antigen Test, Dengue IgG/IgM Combo Test, Dengue NS1 Antigen and IgG/IgM Duo Panel Test, C-reactive Protein Test,HCG Pregnancy Test, LH Test,Troponin I Test,Myoglobin Test,CK-MB Test

(geen merknaam) (NL-CA002-2020-52869)

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

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