CIBG
Ministry of Health, wellbeing and sports

> Return address PO Box 16114 2500 BC The Hague

Lotus NL B.V.
Attn. Mr. X. Wei
Koningin Julianaplein 10
2595 AA The Hague

Date : Aug 18, 2020
Subject : Notification In-vitro diagnostics

Dear Mr. Wei
I hereby acknowledge receipt on 29 April 2020 of the Article 4. 1st paragraph of the Dutch Decree in vitro diagnostics (BIVD) that company name JOYSBIO (Tianjin) Biotechnology Co., Ltd with European authorized Lotus NL B.V. market the product below as an in vitro diagnostic product on the European market.

The product is registered as an in vitro diagnostic under number:

SARS-CoV-2 IgG/Neutralizing antibody Rapid Test Kit(Colloidal Gold) ,
SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold),
Immunochromatography analyzer (no brand name) (NL-CA002-2020-53008)

Tuberculosis Antibody Test Kit (Colloidal Gold) ,
Mycoplasma Pneumonia IgM Antibody Test Kit (Colloidal Gold),
Treponema Pallidum Antibody Test Kit (Colloidal Gold),
Morphine/Methamphetamine/Ketamine Test Kit (Colloidal Gold)
(no brand name) (NL-CA002-2020-53009)

It means that you have fulfilled your obligation under Article 4 of the BIVD.

In all further correspondence regarding the above-mentioned product, I request that you state this number. No further rights can be derived from this number, it only serves to facilitate the administrative notification.

The registration of in vitro diagnostics as a medical device under the Classification Criteria (Annex II) to Directive 98/79/EC on medical devices for in vitro diagnostics is subject to possible revisions of European regulations on the classification of medical devices and to advancing scientific understanding (see Article 10 (1) of Directive 98/79/EC).

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Information about:
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registration number:
CIBG-20204011

Attachments

Date of Application
Aug 13, 2020

Correspondence should only be addressed to the return address, stating the date and reference of this letter.

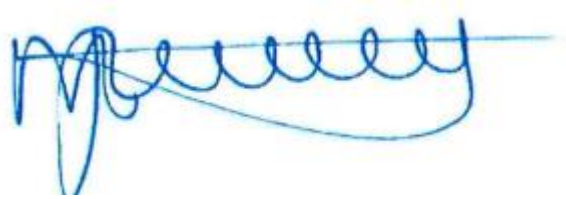
Notification of in vitro diagnostic medical devices implies that the manufacturer, JOYSBIO (Tianjin) Biotechnology Co., Ltd has affixed the CE conformity marking to the relevant product before placing it on the market in an EU Member State. In this way, Lotus NL B.V. guarantees that the in vitro diagnostic complies with the essential requirements as included in Annex I to Directive 98/79/EC (and in the corresponding part 1 of the Decree)

For the sake of completeness, we would like to point out that an in vitro diagnostic must meet the requirements of the BIVD. The BIVD is based on Directive on in vitro diagnostics, 98/79/EC. In particular, we would like to point out the Dutch language requirement as it applies in the Netherlands, the requirements for keeping the technical documentation at their disposal and the duty to have a Post Marketing Surveillance and Vigilantite system.

Finally, I note that with your notification - the administrative notification as a manufacturer - and this letter is no judgment on the status or qualification of your product: notation does not mean that there is actually an in vitro diagnostic within the meaning of this legislation and regulations.
Where appropriate, the Health and Youth Inspectorate (IGJ), responsible for monitoring compliance with the status of a product determined by or under the law, may take a position on the status of a product, where, according to established case law, it is ultimately up to the national court to determine whether a product falls under the definition of in vitro diagnosticum.

The Minister for Medical Care and Sport, on behalf of this,

Department head
Farmatec



Mr. M.J. van de Velde