File No: CE-TCF-007

EC Declaration of Conformity

Regarding In Vitro Diagnostic Directive (98/79/EC)

Manufacturer:

Name:Jiangsu Medomics medical technology Co.,Ltd
Address:F3,Building C,No.3-1 Xinjinhu road,Jiangbei new area, Nanjing,China

EC Representative

Name:R Sight B.V.
Address: Roald Dahllaan 47, 5629 MC, Eindhoven, the Netherlands

Product

Name:

1）SARS-CoV-2 antigen Test Kit (LFIA)
Type:I / II / III/ IV

2）SARS-CoV-2 antigen Test Kit (ELISA)
Type:I / II /BMI /BMII

3）SARS-CoV-2 Neutralizing antibody Test Kit (ELISA)
Type:I / II / III/BMI /BMII/BMIII

4）SARS-CoV-2 Neutralizing antibody Test Kit (LFIA)
Type: I / II / III/IV/V

5）SARS-CoV-2 Neutralizing antibody Test Kit (ELISA)
Type:96Tests/Kit

6）COVID-19 IgM-IgG Rapid Test
Type:1 pc/box

7）SARS-CoV-2 & Influenza A/B Antigen Combo Rapid Test Kit (LFIA)
Type:I / II / III

Classification: IVDD Others
Conformity Assessment Route: IVDD 98/79/EC Annex III
We confirm our product can meet the requirement of In Vitro Diagnostic Medical Devices Directive (98/79/EC) and the following harmonized standards.

EN ISO 14971:2019	EN ISO 15223-1:2016	EN ISO 18113-1:2011
EN ISO 18113-3:2011	ISO 13485:2016	EN 13612:2016

Signature: Zong Zhi Chai

Place and Date of issued: Nanjing. China March 10th, 2021

CIBG
Ministry of People's Health,
Welfare and Sport

> Return Address: Mailbox No. 16114, 2500 BC Den Haag

R Sight B.V.
To the attention of R. Zhang
Roald Dahllaan 47
5629 MC Eindhoven

Date: February 25th 2021
Regarding: Applying for In-vitro diagnostics

Dear Mrs. Zhang,

On January 16th 2021, according to the first term of Article 4 of the Dutch Decree about the in-vitro diagnostics (BIVD), I received your notification with the name of Jiangsu Medomics medical technology Co., Ltd whereby the European authorized R Sight B.V. would introduce the products listed below as in-vitro diagnostics into the European market.
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The products have been registered as in-vitro diagnostics with the number of:

SARS-CoV-2 & Influenza A/B Antigen Combo Rapid
Medomics (NL-CA002-2021-55568)

With this letter you are informed that you have met the responsibilities according to the Article 4 of BIVD.

In all the further correspondence regarding the aforementioned products, I request you to provide this number. One must not utilize this number for any other rights and this number could only be served to simplify the administrative notification.

The registration of in-vitro diagnostics as a medical device with the Classification standard (Annex II) made by the Guideline 98/79/EG about the medical devices for in-vitro diagnostics is subject to the possible revisions of the European regulation regarding the classification of the medical devices and to the promoting scientific level of insight (See the first term, article 10 of Guideline 98/79/EG).

Farmatec

Address for visiting:
Hoftoren Rijnstraat 50
2515 XP Den Haag

T 070 340 6161

http://hulpmiddelen.farmatec.nl

Information provided by:

medische_hulpmiddelen@
minvws.nl

Our Reference No.:
CIBG-20210258

Attachment
-

Date of Your Application
January 16th 2021

Please send your reply letter only to the return address and inform the date and reference number of your letter.

The notification of the in-vitro diagnostic medical devices shows that the products manufacturer, Jiangsu Medomics medical technology Co., Ltd. has met the CE-conformity of marking to the relevant product before introducing it into the market in an EU Member State. In this way, R Sight B.V. guarantees that the in-vitro diagnostics meet the essential requirements which are introduced in Annex I to Guideline 98/79/EG (and in the replying part 1 of the Decree)

In order to guarantee the completeness of the diagnostic, we want to point out that an in-vitro diagnostic has to meet the requirements of the BIVD. The BIVD is based on the guideline for in-vitro diagnostics, 98/79/EG. In particular, we hope that you should pay attention to the Dutch language requirements as though it would be used in the Netherlands. Moreover, you should also keep the technical documentation available and you are obliged to have a Post Marketing Surveillance and Security System.

Finally, I want to make it clear that your notification - the administrative notification as a manufacturer - and this letter does not give an official judgement about the status or the qualification of your product. The notification does not make a decision that there is actually an in-vitro diagnostic under the circumstances of the present laws and regulations. When it is appropriate, the Inspections of the Healthcare and Youth (IGJ), have the duty to supervise whether or not you should be in compliance with the provisions laid down by the law or the regulations made according to the law. It has the words to make the judgement on the status of a product, which is according to the settled case law, ultimately up to the national court who determines whether or not a product falls within the definition of in-vitro diagnostic.

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

Head of Department
Farmatec

(Signature)
Dr. M.J. van de Velde

R Sight B.V. 13/04/2021