Unofficial translation by CEpartner4U

CIBG
Ministry for Public Health, Welfare and Sport
> Return Address P.O. box 16114 2500 BC The Hague The Netherlands

CEpartner4U B.V.
Attn. Mr R. Nusselder
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Farmatec

Visiting Address:
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Information:
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Date: November 25, 2022
Subject: your notification of in-vitro diagnostics

Our reference:
CIBG-20226468

Attachments:
-

Your request
October 24, 2022

Correspondence exclusively to above return Address, indicating the date and reference of this letter.

Dear Mr Nusselder,

Herewith I acknowledge the receipt on October 24, 2022 of the notification of the in-vitro diagnostic product that company MagBio Genomics Inc., with European representative Cepartner4u B.V., wants to place on the market as manufacturer, according to Regulation (EU) 2017/746 (IVDR).
The products are registered under the following reference. I request you to provide this reference in all future correspondence regarding these products and have it available during phone calls.

DNA/RNA isolation
MagBio - DNA/RNA isolation (NL-CA002-2022-73883)
Sequencing reagents
MagBio - Sequencing reagents (NL-CA002-2022-73884)

I would like to point out that in-vitro diagnostic products that are marketed according to the IVDR, must have a Unique Device Identification (UDI) number[1] and that manufacturers, authorized representatives and importers must be registered[2] in the European database on medical devices (Eudamed). Annex VI of the IVDR contains the information to be provided during the registration.
At the moment, Eudamed is not yet in use, so concerning the above it is sufficient that you have registered your product in accordance with current laws and regulations.

As soon as Eudamed is fully operational, it is expected that the manufacturer or its authorized representative registers the above in-vitro diagnostic product in Eudamed within eighteen months.[3]

[1] On the basis of art. 26 IVDR.
[2] On the basis of art. 28 IVDR.
[3] https://www.camd-europe.eu/wp-content/uploads/2018/05/FAQ_IVDR_180117_V1.0-1.pdf. See question and answer number 20.

Finally I point out that with your notification – the administrative notification as manufacturer – and this letter there is no judgement about the status of classification of your product: notification does not mean that there is a confirmation of an actual in-vitro diagnostic product under the present laws and directives. In occurring cases the 'Inspection of Public Health', in charge of supervision on fulfilment of the law, can take a point of view on the status of the product according to the consisting jurisprudence. Whereby at the end it is up to the national judge to decide whether a product comes under the definition of an in-vitro diagnostic product.

The Minister of Public Health, Welfare and Sports,
On behalf of the above,

Department Head
Farmatec

Dr. M.J. van de Velde