GaDia SA
Percevent Ducrest
Route de l`Ile-aux-Bois 1A
1870 Monthey

Bern, 21 February 2022

Notification according to Art 6. of the Medical Devices Ordinance (MedDO)[1] respectively Art. 10 of the European Directive 98/79/EC
Product(s): 51988 Multiple Aspergillus species antigen IVD, kit, enzyme immunoassay (EIA);

Acknowledgement of receipt

Dear Sir,

Swissmedic (Competent Authority No. CH/CA01) hereby acknowledges the receipt of your notification dated 16.02.2022 for the above-mentioned product(s).

The obligation of notification for the above mentioned product(s) according to Art 6. of the Swiss Medical Devices Ordinance (MedDO) respectively Art. 10 of the European Directive 98/79/EC is thus fulfilled.

This acknowledgement of receipt does not, however, constitute either an attestation of conformity, or an approval, or a quality assessment of the product(s). With this acknowledgement, Swissmedic merely takes knowledge of the fact that the notifying person placing medical devices on the market in Switzerland or in a treaty country does so at her own responsibility.

[1] Medical Devices Ordinance of 17 October 2001; SR 812.213

Please note that we have entered the following data in our records for the notified product. For future contact or correspondence, please always quote the notification number provided below:

Notification No.:	**CH-202202-0039**
Date of Notification:	**16.02.2022**
Classification of IVD:	**IVD Other**
GMDN / EDMS Code:	**51988**
Generic Device Group Term:	**Multiple Aspergillus species antigen IVD, kit, enzyme immunoassay (EIA)**
Manufacturer's Product Name:	
Manufacturer:	**GaDia SA**
Notified Body:	

In the context of additional monitoring, Swissmedic reserves the right to ask for supplementary documentation or information.

Swissmedic has uploaded the notification information to Eudamed, the European Databank on Medical Devices.

Yours sincerely,

Swissmedic – Swiss Agency for Therapeutic Products
Division Medical Devices Operations & Hospitals

Carulli Amico Sabina PNOFJW
21.02.2022

Info: admin.ch/esignature | validator.ch

Sabina Carulli Amico
Specialist assistant