

Bordier Affinity Products SA
Dr. Nicolas Beyls
Chatanerie 2
1023 Crissier

Bern, 20 January 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): 52125 Anisakis species immunoglobulin G (IgG) antibody IVD, kit, enzyme immunoassay (EIA);

Acknowledgement of receipt

Dear Sir,

Swissmedic (Competent Authority No. CH/CA01) hereby acknowledges the receipt of your notification dated 04.01.2022 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:

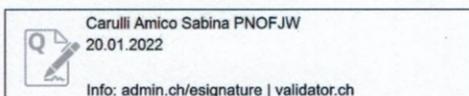
Notification No.:	CH-202201-0009
Date of Notification:	04.01.2022
Classification of IVD:	IVD Other
GMDN / EDMS Code:	52125
Generic Device Group Term:	Anisakis species immunoglobulin G (IgG) antibody IVD, kit, enzyme immunoassay (EIA)
Manufacturer's Product Name:	
Manufacturer:	Bordier Affinity Products 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 Data-bank on Medical Devices.

Yours sincerely,

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



Sabina Carulli Amico
Specialist assistant