

Bordier Affinity Products SA  
Dr. Nicolas Beyls  
Chatanerie 2  
B.P. 186  
1023 Crissier

Bern, 5 May 2022

**Notification according to Art 6. of the Medical Devices Ordinance (MedDO)<sup>1</sup> respectively Art. 10 of the European Directive 98/79/EC**

**Product(s): 52133 Ascaris lumbricoides immunoglobulin G (IgG) antibody IVD, kit, enzyme immunoassay (EIA);**

### **Acknowledgement of receipt**

Dear dear Sir,

Swissmedic (Competent Authority No. CH/CA01) hereby acknowledges the receipt of your notification dated 03.05.2022 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.

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<sup>1</sup> 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.:	<b>CH-202205-0023</b>
Date of Notification:	<b>03.05.2022</b>
Classification of IVD:	<b>IVD Other</b>
GMDN / EDMS Code:	<b>52133</b>
Generic Device Group Term:	<b>Ascaris lumbricoides immunoglobulin G (IgG) antibody IVD, kit, enzyme immunoassay (EIA)</b>
Manufacturer's Product Name:	
Manufacturer:	<b>Bordier Affinity Products SA</b>
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