

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

Bern, 31 August 2017

Notification according to Art 6. of the Medical Devices Ordinance (MedDO)¹ respectively Art. 10 of the European Directive 98/79/EC
Product(s): 15.05.10.04 Echinococcus;

Acknowledgement of receipt

Dear Madam, dear Sir,

Swissmedic (Competent Authority No. CH/CA01) hereby acknowledges the receipt of your notification dated 31.07.2017 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-201708-0010
Date of Notification:	31.07.2017
Classification of IVD:	IVD Other
GMDN / EDMS Code:	15.05.10.04
Generic Device Group Term:	Echinococcus, Parasitology (antibodies, Echinococcosis)
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

A handwritten signature in blue ink, appearing to read "ASchlegel".

Dr. Andreas Schlegel
Scientific Officer