

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

Bern, 13 August 2018

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 08.08.2018 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-201808-0008 |
| Date of Notification: | 08.08.2018 |
| Classification of IVD: | IVD Other |
| GMDN / EDMS Code: | 15.05.10.04 |
| Generic Device Group Term: | Echinococcus |
| 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



Dr. Andreas Schlegel
Scientific Officer