swissmedic

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

Bern, 26 March 2012

Notification according to Art 6. of the Medical Devices Ordinance (MepV) respectively Art. 10 of the European Directive 98/79/EC
Product(s): 15.05.10.01 Entamoeba histolytica

Dear Sir or Madam,

Acknowledgement of receipt

Swissmedic (Competent Authority No. CH/CA01) hereby acknowledges the receipt of your notification dated 01.03.2012 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 (MepV) respectively Art. 10 of the European Directive 98/79/EC is thus fulfilled.

This acknowledgement of receipt is neither a conformity certificate, an approval nor a quality assessment of the product(s). With this confirmation, Swissmedic takes knowledge of the fact that the notifying person placing medical devices onto the Swiss market or treaty countries does so at their own responsibility.

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-201202-0033**
Date of Notification:	**01.03.2012**
Classification of IVD:	**IVD Other**
GMDN / EDMS Code:	**15.05.10.01**
Generic Device Group Term:	**Entamoeba histolytica**
Manufacturer's Product Name:	
Manufacturer:	**Bordier Affinity Products SA**
Notified Body:	

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

Yours sincerely,

Swissmedic – Swiss Agency for Therapeutic Products
Division Medical Devices

Inspector

M. Bärtsch

Dr. Martin Baertsch

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