

Medical Devices Division

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14 March 2005

Notification according to Art 6. of the Swiss Medical Devices Ordinance (MepV) respectively Art. 10 of the European Directive 98/79/EC Product(s): Other Parasitology, 1505109000

Acknowledgement of receipt

Swissmedic (Competent Authority No. CH/CA01) hereby acknowledges the receipt of your notification dated 08.03.2005 for the above mentioned product(s). 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 registration number provided below:

Registration No.:	H-CH/CA01/IVD/10285
Date of Registration:	14.03.2005
Classification of IVD:	Other Device
EDMS / GMDN Code:	1505109000
Generic Device Group Term:	Other Parasitology
Manufacturer's Product Name:	
Manufacturer:	Bordier Affinity Products SA
Notified Body:	

Empfangsbestätigung (e) H-CH_10285.doc

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. 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.

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

Yours sincerely,

Swissmedic, Swiss Agency for Therapeutic Products Medical Devices Division

Dr Jean-François Sauter

Scientific Officer