swissmedic

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13 July 2007

Notification according to Art 6. of the Swiss Medical Devices Ordinance (MepV) respectively Art. 10 of the European Directive 98/79/EC
Product(s): Schistosoma, 1505100600

Acknowledgement of receipt

Swissmedic (Competent Authority No. CH/CA01) hereby acknowledges the receipt of your notification dated 12.07.2007 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/17983**
Date of Registration:	**13.07.2007**
Classification of IVD:	**Other Device**
EDMS / GMDN Code:	**1505100600**
Generic Device Group Term:	**Schistosoma**
Manufacturer's Product Name:	**--**
Manufacturer:	**Bordier Affinity Products SA**
Notified Body:	**--**

Empfangsbestätigung (e) H-CH_17983

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
Scientific Officer

i.V.
Brigitte Gautschi