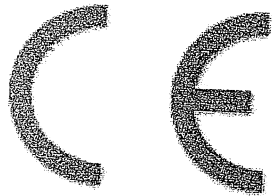


AUTOBIO DIAGNOSTICS CO., LTD
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Zhengzhou, China 450016
Tel: +86 371 6798 5313
Fax: +86 371 6798 5804
www.autobio-diagnostics.com



Declaration of Conformity

According to annex III of the Council Directive 98/79/EC on in vitro diagnostic medical device
We,

Autobio Diagnostics Co. Ltd
Contacter: Mr. Xin Sun
Registered Address:
No. 87 Jingbei Yi Road
National Eco & Tech Development Area
Zhengzhou
China
450016

Declare under our sole responsibility that the following in vitro diagnostic medical devices other
than those covered by annex II and devices for performance evaluation

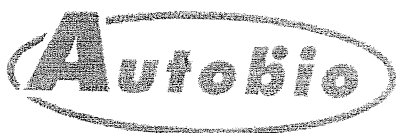
See annex list of products

Meet the provisions of the Council Directive 98/79/EC concerning medical devices which apply to
them.

- Undersigned declares to fulfill the obligations imposed by Annex III section 2 to 5:
- availability of the technical documentation set in Annex III (section 3), allowing the assessment of conformity of the product with the requirements of the Directive.
 - the manufacturer shall take necessary measures to ensure that the manufacturing process follows the principles of quality assurance as appropriate for the products manufactured (Annex III section 4).
 - the manufacturer shall institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase and to implement appropriate means to apply any necessary corrective actions (Annex III section 5).

Conformity assessment was performed according to Article 9 (7) and Annex III, section 3.

Our current Quality System is formatted to international standards:




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ISO 9001:2008
ISO 13485:2003

Signatory established within the EU who has been empowered to enter into commitments on our behalf:

Autobio Diagnostics Co. Ltd
Registered Address:
No. 87 Jingbei Yi Road
National Eco & Tech Development Area
Zhengzhou
China
450016
Phone: +86-371-66785303
Fax: +86-371-62005736
E-mail: sunxin@autobio.com.cn
Mr. Xuewei Wu
Position: General Manager

Signature: 

Date: September 22, 2011



European Authorized Representative (E.A.R.)
Obelis S.A.

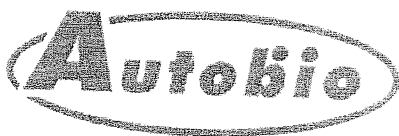
Registered Address:
53, Boulevard Général Wahis
B-1030-Brussels, Belgium
Phone : +32.2.732.59.54
Fax : +32.2.732.60.03
E-mail : mail@obelis.net
Mr. Gideon Elkayam
Position: General Manager

Signature: 
G. ELKAYAM
CEO

Date: 8/12/2011 Obelis s.a. - O.E.A.R.C.
Registered Address :
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List of Products Covered by this Declaration

No.	Device Name
1	T3 ELISA
2	T4 ELISA
3	TSH ELISA
4	FT3 ELISA
5	FT4 ELISA
6	BV
7	Vaginitis Multitest
8	Bi-state Blood Culture Bottle
9	Anaerobic Blood Culture Bottle
10	<i>Mycoplasma</i> (UU-MH) Culture Broth
11	<i>Mycoplasma</i> IES

 Nov. 16, 2011

