

Fecal Occult Blood (FOB) Diagnostic Kit (Colloidal Gold) Technical File (II)	Document No	Version	Page
	ALK-CE-FOB	B	1/2

II Declaration of Conformity

Manufacturer: Atlas Link (Beijing) Technology Co., Ltd.

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Beijing, China

Tel: +86-10-8890 9112 Fax: +86-10-8890 9115

Website: <https://www.invitro-test.com>

European Representative: Name: MT Promedt Consulting.

Address: Altenhofstr. 80
66386 St. Ingbert
Germany

E-mail: ear@mt-procons.com

Product: Fecal Occult Blood (FOB) Diagnostic Kit (Colloidal Gold)

Classification: Self testing / IVDD Annex IV. section 3

Conformity Assessment Route: Annex IV (excluding 4 and 6)

Declaration of conformity: We herewith declare that the above mentioned products meet the provisions of EC Council Directives and Standards for Medical Devices. All supporting documentations is retained under the premises of Atlas Link (Beijing) Technology Co., Ltd.

General applicable directives: ISO13485

IVDD98/79EC

(Details of Directives and Standard Applied, see: III
Standards Used).

Notified Body: TÜV Product Service GMBH NO. 0123

Ridlerstraße 65, 80339 München

Fecal Occult Blood (FOB) Diagnostic Kit (Colloidal Gold) Technical File (II)	Document No	Version	Page
	ALK-CE-FOB	B	2/2

EC Certificate: No.V1 057995 0009 Rev.01

(Expiry date of the Certificate :2021-05-08)

Start of CE-Marking: May 12th,2011 LOT: 110226LS

Place, Date of Issue: Beijing, APR 03th, 2019

General Manager: Chen Jianjiang

