Certificate of Analysis

(RE TYPED COPY OF ORIGINAL CERTIFICATE)

Date:	2014-09-29

Product:	Chlamydia Rapid Test Card

PRODUCT CODE/ ART.-NO.	LOT NUMBER	EXPIRATION DATE	QUANTITY	PHYSICAL APPEARANCE
004A170	004A170-9114	2016-09	10.000	conforms

PRODUCT TEST RESULTS

ANALYSIS	SPECIFICATIONS	TEST RESULTS
Negative specimens	negative	negative
1.0 x 10^7 org/ml	positive	positive

Further Test Criteria:
Chromatography
Reaction time
Visual testing
Discoloration at C & T Line

PRODUCT MANUFACTURING

The above listed product has been manufactured in accordance with relevant standard (EN ISO 13485:2012/AC:2012).No radioactive material of any kind is utilized in the product, or in the manufacturing of the product.

The above listed product does not contain any virus, reactive by-product of the same, or metabolic by-product of hepatitis A, B, C, or D, or of the antibodies for the human acquired immune deficiency syndrome (AIDS).

If this product is shipped as bulk, ulti med Products (Deutschland) GmbH assumes no responsibility for the packing and label claims.

Management

EC DECLARATION OF CONFORMITY

For the purposes of Annex IV to directive 98/79/EC for In-vitro-Diagnostic medical devices

Manufacturer:	ulti med Products (Deutschland) GmbH, Reeshoop 1, D-22926 Ahrensburg
Product:	Chlamydia Rapid Test Card
Product ID:	004A170
Lot:	004A170-9114
Expiry:	2016-09
Quantity:	10.000
Classification:	IVD Directive 98/79 Annex II List B
Notified Body:	TÜV Süd Product Service GmbH, Ridlerstraße 65, D-80339 Munich
No. Of Notified Body:	0123
Certificate-No:	V1 13 07 55233 036
Date:	2013-07-25
Valid from:	2013-09-19
Valid until	2018-09-18

We hereby declare that the above named In-vitro-Diagnostic medical device are manufactured by us meets the essential requirements of Directive 98/79/EC and is suitable for the intended application. Any accompanying documentation is subject to the manufacture's responsibility.

Laws, rules and standards, applied

Directive 98/79/EC	of the European Parliament and of the council of 27 October 1998 in in vitro diagnostic medical devices
EN 1041: 2008/AC:2013	Information supplied by the manufacturer of medical devices
EN ISO 13485: 2012/AC:2012	Medical devices – Quality management systems – Requirements for regulatory purposes
EN 13612: 2002	Performance evaluation of in vitro diagnostic medical devices
EN 13641: 2002	Elimination or reduction of risk of infection related to in vitro diagnostic reagents
EN ISO 14971: 2012	Medical devices – Application of risk management to medical devices
EN ISO 15223-1: 2012	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
EN ISO 18113-1: 2013	In vitro diagnostic medical devices – Information supplied by the manufacturer (labelling) – Part 1: Terms, definitions and general requirements
EN ISO 18113-2: 2013	In vitro diagnostic medical devices – Information supplied by the manufacturer (labelling) – Part 2: In vitro diagnostic reagents for professional use

Ahrensburg, 2014-09-29
ulti med Products (Deutschland) GmbH

Matthias W. Engel
Managing Director

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