Certificate of Analysis

(RE TYPED COPY OF ORIGINAL CERTIFICATE)

Testing Date	2017-07-19

Product	Chlamydia Antigen Test

PRODUCT CODE / ART.-NO.	LOT NUMBER	EXPIRATON DATE	QUANTITY	PHYSICAL APPEARANCE
004A170	004A170-17620	2019-05	5.520	conforms

PRODUCT TEST RESULTS

ANALYSIS	SPECIFICATIONS	RESULTS
Negative Specimens	negative	negative
1.0×10^7 org/ml	positive	positive

PRODUCT MANUFACTURING

The above listed product has been manufactured in accordance with relevant standard (EN ISO 13485:2016).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. 3 to directive 98/79/EC for In-vitro-Diagnostic medical devices

Manufacturer:	ulti med Products (Deutschland) GmbH, Reeshoop 1, D-22926 Ahrensburg
Product:	Chlamydia Antigen Test
Product ID:	004A170
Lot:	004A170-17620
Expiry:	2019-05
Quantitiy:	5.520
Classification:	IVD Directive 98/79 Annex II List B
Notified Body:	TÜV Süd Product Service GmbH, Ridlerstraße 65, D-80339 München
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 fo 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 on in vitro diagnostic medical devices
EN ISO 13485: 2016	Medical devices – Quality management systems – Requirements for regulatory purposes
EN ISO 14971:2012	Medical devices – Application of risk management to medical devices
EN 980:2008	Symbols for use in the labelling of medical devices
EN ISO 18113-1:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) Part 1: Terms, definitions and general requirements
EN ISO 18113-2:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use
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 reagent

Ahrensburg 2017-07-19

ulti med Products (Deutschland) GmbH

CEO

ulti med Products (Deutschland) GmbH
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