

## EC Certificate

Directive 98/79/EC Annex IV, excluding Sections 4 and 6  
Full Quality Assurance System  
In Vitro Diagnostic Medical Devices

Registration No.: HL 60131398 0001

Report No.: 21200072 015

**Manufacturer:** nal von minden GmbH  
Carl-Zeiss-Str. 12  
47445 Moers  
Deutschland

**Products:**

- IVDs for the detection of infectious disease markers
- IVDs for the detection of the tumor marker PSA
- Urine tests for self-testing

(see attachment for products and sites included)

Replaces Certificate, Registration No.: HL 60114562 0001

**Expiry Date:** 2023-11-27

The Notified Body hereby declares that the requirements of Annex IV, excluding section 4 and 6 of the directive 98/79/EC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex IV, section 5 of the aforementioned directive. For placing on the market of List A devices covered by this certificate an EC design-examination certificate according to Annex IV, section 4 and a verification of manufactured products according to section 6 is required.

**Effective Date:** 2018-11-28

**Date:** 2018-11-27

Notified Body



Dipl.-Ing. Sven Hoffmann

**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**  
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 98/79/EC concerning in vitro diagnostic medical devices with the identification number 0197.

**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

**Attachment to  
Certificate**

**Registration No.:** HL 60131398 0001  
**Report No.:** 21200072 015

**Manufacturer:** nal von minden GmbH  
Carl-Zeiss-Str. 12  
47445 Moers  
Deutschland

**Products included:**

In vitro diagnostica for self-testing:

- HCG pregnancy tests
- LH ovulation tests
- Single- and multi-constituent test strips for urinalysis

In vitro diagnostica rapid tests:

- Chlamydia trachomatis Rapid Tests
- PSA Rapid Tests

**Site included:**

nal von minden GmbH  
Friedenstr. 32  
93053 Regensburg  
Germany

**Activities:** Design and development

**Date:** 2018-11-27

**Notified Body**



  
**Dipl.-Ing. Sven Hoffmann**