EC Certificate

TÜVRheinland®

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

Registration No.: HL 1034230-1

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

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

Replaces Certificate, Registration No.: HL 60131398 0001

The Notified Body hereby declares that the requirements of Annex IV, excluding sections 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.

Report No.: 1089328-30

Effective date: 2021-11-16

Expiry date: 2023-11-27

Issue date: 2021-11-16

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Katja Mierisch
TÜV Rheinland LGA Products GmbH
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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.

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47445 Moers
Germany

Products included:

In vitro diagnostica for self-testing:
- HCG pregnancy tests
- LH ovulation tests
- Single- and multi-constituent test strips for urinalysis
- Covid-19 antigen rapid tests

In vitro diagnostica rapid tests:
- Chlamydia trachomatis rapid tests
- PSA rapid tests

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The scope of certification includes the following manufacturing sites:

No.	Location	Scope
/01	nal von minden GmbH Carl-Zeiss-Str. 12 47445 Moers Germany	Design, Development and Manufacture
/02	nal von minden GmbH Friedenstr. 32 93053 Regensburg Germany	Design and Development

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