

EU Certificate

Quality Management System REGULATION (EU) 2017/746 on In Vitro Diagnostic Medical Devices Annex IX Chapter I, Section 2 and 3 and Chapter III

Registration No.: HX 1939197-1

Manufacturer: Attomol GmbH Molekulare Diagnostika
Schulweg 6
03205 Bronkow
Germany

EUDAMED Single
Registration No.: DE-MF-000026028

Products: Products of class C:

GENETIC TESTING

IVR 0402: Devices intended to be used to predict genetic
disease/disorder risk and prognosis
W01060101 - MONOGENETIC DISORDERS
W01060102 - POLYGENETIC DISORDERS
W01060104 - POLYMORPHISMS
W010699 - GENETIC TESTS - OTHER

Authorized representative(s): N/A

The Notified Body hereby declares that the requirements of Annex IX, Chapter I, Section 2 and 3 of the REGULATION (EU) 2017/746 have been met for the listed products. The above named manufacturer has established and applies a quality management system, which is subject to periodic surveillance, defined by Annex IX, Chapter I, Section 3 of the aforementioned regulation. The requirements of Annex IX, Chapter III are fulfilled.

If class D devices are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 4 is required before placing them on the market.

If class B, C or D devices for self-testing or near-patient testing are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 5.1 is required before placing them on the market.

If companion diagnostics are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 5.2 is required before placing them on the market.

Report No.: 1099916-40

Effective date: 2024-05-03

Expiry date: 2029-05-02

Issue date: 2024-05-03



Katja Mierisch
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

This certificate can be validated on <https://www.certipedia.com>

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Precisely Right.

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Annex IX Chapter I, Section 2 and 3 and Chapter III**

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Certificate history		
Revision:	Description:	Issue date:
0	Initial certification	2024-05-03

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