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Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
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BS-IVDR-099

Product Service

# EU Technical Documentation Assessment Certificate (IVDR)

Pursuant to Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices,
Annex IX, Chapter II, Section 4, 5.1
(Class C and B Devices for self-testing and near patient testing)

## No. V74 099371 0018 Rev. 00

**Manufacturer:**

**SPD Swiss Precision Diagnostics GmbH**
47, Route de Saint-Georges
1213 Petit-Lancy, Geneva
SWITZERLAND

SRN Manufacturer - CH-MF-000025175

**Authorized Representative:**

Medical Device Safety Service GmbH
Schiffgraben 41, 30175 Hannover, GERMANY

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has drawn up and presented a Technical Documentation according to Annex II and III of the Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices. Details on devices covered by the Technical Documentation are described on the following page(s).
The Report referenced below summarizes the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX, Chapter II, Section 4, 5.1 of this regulation with a positive result.
In order to place the devices on the market with CE-marking, an EU Quality Management System Certificate pursuant to Annex IX Chapters I and III is necessary in addition to this EU Technical Documentation Assessment Certificate. All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:V74 099371 0018 Rev. 00

**Report No.:** 75959579_TDAR

**Valid from:** 2025-01-29
**Valid until:** 2030-01-28

Marta Carnielli
Head of Certification IVD

**Issue date:** 2025-01-29


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## No. V74 099371 0018 Rev. 00

| | |
|---|---|
| **Classification:** | Class B |
| **Device Group:** | W0102160304 - LH - RT & POC |
| **Basic UDI-DI:** | 4084500DOTB5 |
| **Intended Purpose:** | This product consists of a reusable electronic holder and single use test sticks. It is an automated, at home, self-testing device which semi-quantitatively detects the surge in luteinising hormone (LH) in a woman's urine to identify peak fertility (highest chance of conceiving). The LH surge precedes ovulation by 24-36 hours. |
| **Device(s):** | Clearblue Digital Ovulation Test, Product Code DOT<br><br>Variant Code.....Description<br>UO0026.....DOT with holder 81727396<br>UO0029.....DOT with holder 80777418 |

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|---|---|
| **The validity of this certificate depends on conditions and/or is limited to the following:** | - |

**Revision History:**

| Rev. | Dated | Report | Description |
|---|---|---|---|
| 00 | 2025-01-29 | 75959579_TDAR | Initial issuance |


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# CERT-0202 (DOC-24658) Ver. 0

**Approved By:**

**shanice Njeri-Okusanya** - Author

January 29, 2025 4:10 PM GMT 68d87f31-dfe2-436d-92d2-201e25e11d7e

**Version History:**

| Author | Effective Date | Ver. | Status |
|---|---|---|---|
| shanice Njeri-Okusanya | January 29, 2025 4:10 PM GMT | 0 | Published |