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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, 5.2
(Class C Devices, Companion Diagnostics)

## No. V75 115771 0004 Rev. 00

**Manufacturer:**

**Life Technologies Corporation**
7335 Executive Way
Frederick MD 21704
USA

SRN Manufacturer - US-MF-000023929

**Authorized Representative:**

Life Technologies Europe B.V
2 Kwartsweg, 2665 NN Bleiswijk, THE NETHERLANDS

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, 5.2 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:V75 115771 0004 Rev. 00

**Report No.:** 115771_IVDR_ODxTT-CDx

**Valid from:** 2024-11-27
**Valid until:** 2029-11-26

Marta Carnielli
Head of Certification IVD

**Issue date:** 2024-11-27


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**Classification:** Class C
**Device Group:** W0106 - GENETIC TESTING
**Basic UDI-DI:** 0190302A49756TV

**Intended Purpose:**

The Oncomine™ Dx Target Test is indicated as a companion diagnostic to aid in selecting patients for treatment with the targeted therapies listed in Table 1 in accordance with the approved therapeutic product labelling. The test is a qualitative in vitro diagnostic test that uses high throughput parallel sequencing technology to detect sequence variations (SNVs, deletions, insertions, and fusions) in 46 cancer related genes on DNA and RNA isolated from formalin-fixed, paraffin-embedded (FFPE) tissues using the automated Ion PGM™ Dx Instrument System. Interpretation of assay results for cancer patients is intended to be performed only by healthcare professionals in accordance with professional guidelines in oncology.

Table 1: List of variants for therapeutic use
Non-small cell lung cancer (NSCLC)
- ALK fusion: XALKORI® (crizotinib), ALUNBRIG® (brigatinib)
- BRAF V600E mutations: TAFINLAR® (dabrafenib) in combination with MEKINIST® (trametinib)
- EGFR L858R mutation, EGFR Exon 19 deletions: VIZIMPRO® (dacomitinib)
- EGFR Exon 20 insertions: RYBREVANT™ (amivantamab)
- ERBB2/HER2 Exon 20 insertions, ERBB2/HER2 SNVs: ENHERTU® (trastuzumab deruxtecan)
- RET fusions: RETSEVMO® (selpercatinib)
- ROS1 fusions: XALKORI® (crizotinib)
Cholangiocarcinoma (CCA)
- IDH1 R132C, IDH1 R132G, IDH1 R132H, IDH1 R132L, IDH1 R132S: TIBSOVO® (ivosidenib)
Thyroid cancer (TC)
- RET fusions: RETSEVMO® (selpercatinib)
Medullary thyroid cancer (MTC)
- RET mutations (SNVs, MNVs, and deletions): RETSEVMO® (selpercatinib)

In addition to the genes and targeted therapies listed above, non-CDx sequence variations in 35 DNA genes and 21 RNA genes have either been analytically validated or have representative validation. Safe and effective use of non-CDx variants has not been established for selecting therapies. Results are intended to be used by healthcare professionals as reference. Detailed list for these sequence variations can be found in Oncomine™ Dx Target Test User Guide.

**Device(s):** Oncomine™ Dx Target Test
Ref. No. A65538


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

The Oncomine™ Dx Target Test companion diagnostic device contains non-companion diagnostic claims classified according to Annex VIII rule 3(i). The non-companion diagnostic claims relate to DNA and RNA gene variations described in the Intended Purpose in the IFU. These claims have been assessed in the Technical Documentation assessment performed for the companion diagnostic claims according to Annex IX Chapter II (5.2.). Surveillance will be performed by following the EU Technical Documentation certification approach and not the EU Quality Management System certification approach according to Article 48 (7). The surveillance for the Oncomine™ Dx Target Test Assay Definition File (ADF) software will be performed following the EU Quality Management System certification approach according to Article 48 (7).

**Revision History:**

| Rev. | Dated | Report | Description |
|---|---|---|---|
| 00 | 2024-11-27 | 115771_IVDR_ODxTT-CDx | Initial issuance |


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