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Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
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 113968 0006 Rev. 00

Manufacturer:

Agilent Technologies, Inc.
5301 Stevens Creek Boulevard
Santa Clara CA 95051
USA

SRN Manufacturer - US-MF-000009385

Authorized Representative:

Agilent Technologies Denmark ApS
Produktionsvej 42, 2600 Glostrup, DENMARK

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.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:V75 113968 0006 Rev. 00

Report No.: 72182204

Valid from: 2023-07-25
Valid until: 2028-07-24

Marta Carnielli
Head of Notified Body IVD

Issue date: 2023-07-25

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
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Classification:	Class C
Device Group:	W0102 - IMMUNOCHEMISTRY (IMMUNOLOGY)
Basic UDI-DI:	570057R0301P3007C021901N2
Intended Purpose:	For in vitro diagnostic use

PD-L1 IHC 22C3 pharmDx is a qualitative immunohistochemical assay using monoclonal mouse anti-PD-L1, Clone 22C3, intended for use in the detection of PD-L1 protein in formalin-fixed, paraffin-embedded (FFPE) non-small cell lung cancer (NSCLC), urothelial carcinoma, esophageal cancer, head and neck squamous cell carcinoma (HNSCC), triple-negative breast cancer (TNBC), and melanoma tissues using EnVision FLEX visualization system on Autostainer Link 48.

PD-L1 protein expression in NSCLC is determined by using Tumor Proportion Score (TPS).*

PD-L1 protein expression in urothelial carcinoma, esophageal cancer and TNBC is determined by using Combined Positive Score (CPS).*

PD-L1 protein expression in HNSCC is determined by using CPS and/or TPS.*

PD-L1 protein expression in melanoma is determined by using Melanoma Score (MEL Score). PD-L1 IHC 22C3 pharmDx is not required for companion diagnostic use in melanoma tumor tissues.*

Companion diagnostic indications:
PD-L1 IHC 22C3 pharmDx is indicated as an aid in identifying patients for treatment with the therapies for the tumor indications and their specific PD-L1 expression levels listed below.

KEYTRUDA® (pembrolizumab)**

- NSCLC; TPS ≥ 1%, TPS ≥ 50%
- Urothelial Carcinoma;CPS ≥ 10
- Esophageal Cancer;CPS ≥ 10
- HNSCC; CPS ≥ 1 ;TPS ≥ 50%
- TNBC;CPS≥ 10

LIBTAYO® (cemiplimab)***

- NSCLC;TPS ≥ 50%

*See section 13 of IFU.

**See the KEYTRUDA® product label for PD-L1 expression cutoff values and specific clinical circumstances guiding therapy.

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	***See the LIBTAYO® product label for specific clinical circumstances guiding PD-L1 testing.
Device(s):	PD-L1 IHC 22C3 pharmDx (P/N SK00621-2)
The validity of this certificate depends on conditions and/or is limited to the following:	The Agilent PD-L1 IHC 22C3 pharmDx companion diagnostic device contains non-companion diagnostic claims classified according to Annex VIII rule 3(h). These claims have been assessed in the Technical Documentation assessment performed for the companion diagnostic claim 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 approach according to Article 48 (7) & (9).

Revision History:

Rev.	Dated	Report	Description
00	2023-07-25	72182204	Initial issuance

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