

The certification body of TÜV Informationstechnik GmbH certifies as a result of the certification decision as of 2022-07-19 according to Art. 42 Abs. 5 GDPR, that

BDS Digital Health Solutions GmbH
Wilhelmstraße 17
34346 Hann. Münden, Germany

as controller in accordance with Art. 4 No. 7 GDPR within the scope of Germany, data processing by information processing systems

MedKitDoc Videosprechstunde

is operated in accordance with appendixes 1 (permitted use) and 2 (exclusions of use) in conformity with the requirements of EU Regulation 2016/679 (GDPR) and the additional requirements of the data protection supervisory authorities and is monitored during the term of the certificate

The information of the data protection supervisory authority NRW according to Art. 43 para. 5 GDPR has taken place on: 2021-09-13.

Evaluation basis: Zertifizierungsprogramm DS-GVO, Version 0.97
Trusted Site Data Privacy, Version 1.0



Last on-site audit day:
2021-06-10

Monitoring until:
2022-09-16

Certificate validity:
2021-09-16 – 2024-09-16

Certificate ID: 5601.21

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Essen, 2022-07-19

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Certificate



Certification Scheme and Monitoring

The certification body of TÜV Informationstechnik GmbH performs its certification on the basis of the following certification scheme:

- German document: „Zertifizierungsprogramm DSGVO der TÜV Informationstechnik GmbH“, version 0.97 as of 2021-08-11, TÜV Informationstechnik GmbH

Transfer note

This certificate was issued by the certification body of TÜV Informationstechnik GmbH, which is already accredited according to ISO/IEC 17065 and is still in the accreditation process (including evaluation of the certification scheme).

According to Annex 31b to the Federal Medical Insurance Contract (BMV-Ä) "Vereinbarung über die Anforderungen an die technischen Verfahren zur Videosprechstunde gemäß § 365 Absatz 1 SGB V vom 21. Oktober 2016 in der Fassung vom 15. Juni 2022", this certificate may can be used for a transitional period up to December 31, 2022, subject to any changes and extensions of the transitional period of Annex 31b to the Federal Medical Insurance Agreement (BMV-Ä).

The application number at the DAkkS is: PP-12022-01.

According to the certification scheme, the conformity of the certification subject is monitored annually within the term of the certificate.

The next planned surveillance shall take place by 2022-09-16 at the latest.

Certification Subject

The certification subject is data processing by information processing systems:

- MedKitDoc Videosprechstunde

of the operator

- BDS Digital Health Solutions GmbH in 34346 Hann. Münden, Germany, Wilhelmstraße 17

and its branches

- No branches

Field of application (permitted use) and exclusions of use

The certification subject is intended exclusively for the following field of application:

- The certification subject “MedKitDoc Videosprechstunde” of the company “BDS Digital Health Solutions GmbH” is an online video consultation in real time within the framework of synchronous communication (peer-to-peer) between a doctor / alternative practitioner and a patient known to him.

This includes:

- Interfaces to the streaming provider,
- Interfaces to the servers used,
- Interfaces to the databases used.

The following use of the certification subject is explicitly excluded:

- See appendix 2 „exclusions of use“

Evaluation basis

The evaluation was based on the following requirements:

- EU Regulation 2016/679 (GDPR) including the additional requirements of the data protection supervisory authority.
- Criteria catalog: Trusted Site Data Privacy, version 2.0 as of 2021-05-05, TÜV Informationstechnik GmbH.

Evaluation Report

The evaluation result is set out in the following report:

- Evaluation Report Trusted Site Data Privacy, MedKitDoc Videosprechstunde, version 2.0 as of 2021-08-16, TÜV Informationstechnik GmbH.

Evaluation result

- The on-site audit was conducted during the period from 2021-06-08 until 2021-06-10 (last on-site audit day).
- The certification subject fulfills all applicable requirements from EU Regulation 2016/679 (GDPR) and the criteria catalog Trusted Site Data Privacy, version 2.0.

The recommendations stated in the evaluation report must be observed.

Certification decision

The result of the certification decision on 2021-07-19 showed that the applicant, its data processing and the following branches

- No Branches

meet all applicable requirements for the operational environment and observing the exclusions of usage.

The reasons for granting the certificate were provided to the data protection supervisory authority NRW in accordance with Art. 43 (5) DS-GVO on 2021-09-13.

exclusions of use

The following usage of the certification subject is explicitly excluded:

- Interfaces to other networked medical products or medical devices for remote treatment offered by MedKitDoc (e. g. stethoscope or digital blood pressure measuring device) as well as additional functions (provision of doctor's letters and diagnostic results, images, etc.) are not part of the certification subject.