

The certification body of TÜV Informationstechnik GmbH certifies as a result of the certification decision as of 2021-09-16 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 Attachments 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 – 2022-09-16

**Certificate ID: 5601.21**

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Essen, 2021-09-16

Dr. Christoph Sutter  
Head of Certification Body

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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 25. Februar 2021", this certificate may can be used for a transitional period up to December 31, 2021, 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 and exclusions of usage**

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 „Usage exclusions“

## **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 2021-09-16 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.

## Usage exclusions

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.