

Certificate

The certification body of TÜV Informationstechnik GmbH certifies as a result of the certification decision as of 2023-05-16 according to Art. 42 Para. 5 GDPR, that

Medgate AG
Dufourstrasse 49
4052 Basel, Switzerland

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

Medgate Videokonsultationssystem Version 2.0

is operated in accordance with appendices 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 2023-04-26.

Evaluation basis: Zertifizierungsprogramm DS-GVO, version 0.97
Trusted Site Data Privacy, Version 2.4

The appendices 1 and 2 to the certificate are part of the certificate with the ID 5616.23.

Essen, 2023-05-16

Dr. Christoph Sutter, Head of Certification Body



Certificate validity:
2023-05-16 – 2024-05-16

Last evaluation day:
2023-03-31

Monitoring until:
2024-05-16



Certification scheme and monitoring

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

- German document: "Zertifizierungsprogramm DS-GVO 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) and authorisation procedure in accordance with § 39 BDSG (German Federal Data Protection Act).

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 19. Dezember 2022", this certificate may can be used for a transitional period up to 31. December 2023, 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 DAKs 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 2024-05-16 at the latest.

Certification target

Video consultations are basically defined as synchronous communication between a doctor and a patient known to him, via the technical equipment available to the patient (peer-to-peer), if necessary with assistance, e.g. by a reference person, in the sense of an online video consultation in real time, which the doctor can offer the patient.

The certification target in the sense of the technical procedure for video consultation in accordance with Annex 31b to the Bundesmantelvertrag-Ärzte (BMV-Ä) with the associated interfaces for the processing of personal data is the data processing by the information-processing system:

- Medgate video consultation system version 2.0

It consists of the telemedical function: implementation of online video consultations. The evaluation covers the certification target, the conduction of the video consultation (medical consultation) and its termination.

The operator of Medgate Videokonsultationssystem, Version 2.0 is the company:

- Medgate AG in 4052 Basel, Dufourstrasse 49, Switzerland

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 area of application results from Annex 31b to the Bundesmantelvertrag-Ärzte (BMV-Ä): telemedical, synchronous peer-to-peer communication of the online video consultation between the doctor and the patient known to him.

The following use of the certification subject is explicitly excluded:

- See appendix 2 "Usage exclusions"

Details on the scope of use and the terms of use are listed in the short expert report, which is available to the public.

Short expert report (public)

- German document: "Kurzgutachten über die Ergebnisse der Zertifizierung 5616.23, Version 2.0 as of 2023-04-20" TÜV Informationstechnik GmbH

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 (German document): "Trusted Site Data Privacy Kriterienkatalog für Prüfungen der Konformität einer IT-Lösung zur Europäischen Datenschutzgrundverordnung", version 2.4 as of 2021-12-15, TÜV Informationstechnik GmbH

Evaluation report

The evaluation result is set out in the following report:

- German document: “Evaluierungsbericht Trusted Site Data Privacy, Medgate Videokonsultationssystem Version 2.0”, version 2.0 as of 2023-03-31, TÜV Informationstechnik GmbH.

Evaluation result

The evaluation was conducted during the period from 2021-06-24 until 2023-03-31 (last evaluation day).

The certification subject fulfills all applicable requirements from EU regulation 2016/679 (GDPR) and the criteria catalog Trusted Site Data Privacy, version 2.4.

The recommendations stated in the evaluation report must be observed.

Certification decision

The result of the certification decision on 2023-03-16 showed that the applicant, its data processing and the above-mentioned branches meet all applicable requirements for the operational environments and observing the usage exclusions.

The reasons for granting the certificate were provided to the data protection supervisory authority NRW (North Rhine-Westphalia) in accordance with Art. 43 Para. 5 GDPR on 2023-04-26

Invalid from 2024-07-01

Usage exclusions

The following usage of the certification target is explicitly excluded:

- All functions and data processing that are not part of the telemedical, synchronous peer-to-peer communication of the online video consultation.
- Interfaces to other additional functions offered by Medgate AG, such as the provision of doctor's letters, diagnostic findings, calendar functions, images, etc.

Invalid from 2024-01-01