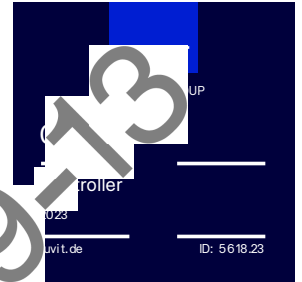


Certificate



The certification body of TÜV Informationstechnik GmbH certifies as a result of the certification decision as of 2023-01-19 according to Art. 42 Abs. 5 GDPR, that

Huma Therapeutics Limited
21-24 Millbank, Millbank Tower
London SW1P 4QP, United Kingdom

Certificate validity:
 2023-01-19 – 2026-01-19

Last evaluation day:
 2023-01-11

Monitoring until:
 2024-01-19

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

Huma - Videosprechstunde

is operated in accordance with applicable law (permitted use) and 2 (exclusions of use) in conformity with the requirements of the General Data Protection 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 been published on: 2023-01-16.

Evaluation according to Zertifizierungsprogramm DS-GVO, version 0.97
 Trusted Site Data Privacy, Version 2.5

The appendices 1 and 2 to the certificate are part of the certificate with the ID 5618.23.

Essen, 2023-01-30

Dr. Christoph Sutter, Head of Certification Body

To Certificate



Certification scheme and monitoring

The certification body of TÜV Informationstechnik GmbH performs its certification based on 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 TÜV Informationstechnik GmbH, which is already accredited according to ISO/IEC 17065 and is currently in the accreditation process (including evaluation of the certification scheme) and authorized 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 Voraussetzungen zur Videosprechstunde gemäß § 365 Absatz 1 SGB V vom 21. Oktober 2016 in der Fassung vom 15. Juni 2022”, this certificate may 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 is: 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 surveillance shall take place by 2024-01-19 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 is the data processing by information-processing systems of Huma - Videosprechstunde (implementation of online video consultation) between doctors and patients. The data processing is realised by the following components:

- Mobile Android App, version 1.23.0
- Mobile iOS App, version 1.23.0

- Telemedicine function of the Huma Web Portal, version 1.0

and by the interfaces of the above applications:

- API interface.

The mobile applications are used on the patient side to set up a video session on the doctor's side, this is done with the help of the Huma Web Portal.

The following external components and associated interfaces are necessary for the operation of the certification target, but are not part of it:

- Twilio infrastructure components
- Huma infrastructure components (e.g. AWS system)
 - Network Load Balancer
 - Managed Kubernetes
 - Managed MongoDB Atlas databases
 - Redis
 - S3 Bucket
 - Cloudfront CDN
 - Mailgun

The operator of Huma - Video Sprechstunde is the company:

- Huma Therapeutics Ltd in London SW1P 4QP, 21-24 Millbank, Millbank Tower, United Kingdom

and its branches:

- No branches

Field of application and exclusions of usage

The certification target 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 target 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 5618.23, Version 2.0 as of 2023-01-11, 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 Datenschutzgrundsatzverordnung”, version 2.5 as of 2022-04-25, TÜV Informationstechnik GmbH

Evaluation report

The evaluation result is set out in the following report:

- German document: “Evaluierungsbericht zur Zertifizierung der Site Data Privacy, Huma - Videosprechstunde”, version 2.0 as of 2023-01-11, TÜV Informationstechnik GmbH.

Evaluation result

The evaluation was conducted during the period from 2021-08-17 until 2023-01-11 (last evaluation day).

The certification includes all applicable requirements from EU Regulation 2016/679 (GDPR) and the criteria catalog Trusted Site Data Privacy, version 2.5.

The recommendations stated in the evaluation report must be observed.

Certification decision

The result of the certification decision on 2023-01-19 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 (5) GDPR on 2023-01-16.

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 functions of the Huma Web Portal and other functions offered by Huma Therapeutics Limited, such as patient monitoring (e.g. recording heart rate) or the maintenance of notes, etc.

Invalid from 2023-09-13