



Regulation on data protection

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CE Certiso

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Regulation on data protection**1 Principles**

CE Certiso Kft. is dedicated to protection of personal data. Present regulation is part of the Quality Management System documentation of CE Certiso Kft., which has been prepared taking into account the GDPR and with the claim to conform according to it. Our regulation on data protection has been prepared based on the Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation).

During its activity, CE Certiso Kft. pays emphasized attention to handle and preserve personal data only until it is necessary required. CE Certiso Kft. must grant every device or resource stated in the GDPR for the persons in question, which serve to control their personal data.

In case of personal data, CE Certiso Kft. is the responsible for the data management. headquarter: H-2092 Budakeszi, Erdő utca 101., General Manager: Valter, PAPP Dr.), accessibility: +36-23-880-830

Data processing is performed based on legislative obligation alone and purpose-bound. (cases of tax and social assurances, determination of competences, contact information in case of conformity assessment procedure)

data processor is who is working with personal data on behalf of the data manager. A CE Certiso Kft. can provide personal data for third party for data processing only by its legislative obligation (Competent Authority, tax authority, accountant).

2 Personal data handled can come from the following sources

- data of full-time employees and employees with mandatory contract fixed in the contract of employment;
- data of contact person of our clients;
- data of contact person of our contractual partners;
- data of contact person of our inquiries.

Besides the above written, CE Certiso Kft. does not collect, handle and preserve personal data. Through its website, (cecertiso.hu) CE Certiso Kft. does not collect data. CE Certiso Kft.. does not ensure opportunity for registration on its website.

3 Actions to follow for the protection of personal data

3.1. CE Certiso Kft. can legally gain personal data only from the following sources

- with the approval of the person in question (employment contract, mandatory contract, declaration);
- contact data given by clients voluntary in order for purpose-bound utilization
- by application of inquiries, demanders of price. Only the type and amount of personal data can be handled which is suitable and necessary by all means for

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the purpose of data management (quotation according to MDD, AIMD, IVDD, MDR, IVDR, ISO 9001, ISO 13485). Majority of the data necessary for a quotation are data of the organization, product or process data which do not fall under the scope of GDPR. However, in order of keeping in touch, name and contact of the inquiry is necessary. Always a minimal circle of data can be managed with which the given task can be performed. These data can be the name, e-mail address and phone number of the inquiring organization's representative.

- Contact data voluntary given by our contractual partners in order of purpose-bound operation.

Besides the above written, CE Certiso Kft. does not collect personal data!

3.2. Safe storage of personal data

CE Certiso Kft. stores personal data electronically and paper-based way.

- Paper-based storing: Place for paper-based storage of documents containing personal data is a lockable cabinet, in the locked office of CE Certiso Kft. Management of CE Certiso Kft. has the only access.
- Place of electronic storage is NAS (Network Attached Storage), property of CE Certiso Kft. NAS is a storage system connected to network. Data stored on NAS can be protected by the proper setting of user permissions. Documents containing personal data are stored in a separate folder to which only the General Manager, the Clinical Leader and the Quality Manager has access.

3.3. Handling of incidents

In case of incident of data protection, as soon as CE Certiso Kft. get knowledge of it, but according to its opportunities in 72 hours it reports towards NAIH and towards the users concerned, if it is possible that the incident possibly has high risk for them. Report of the incident happens through the online surface of NAIH. Responsible person is the General Manager.

3.4. Others

CE Certiso Kft. does not send newsletter or direct marketing information automatically.

If, in case of informing, it is necessary to send newsletters or advertisements, preliminary permission is necessary. Permission can be realized only with the active attitude of the addressee.

4 Legal rights ensured for the person in question

The person in question can

- ask access and information about the handling of his/her data;
- ask correction if any of his/her data is not correct;
- ask limitation of data management;



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- make his/her data deleted, if the legal basis of data management has been ended (so-called “right to be forgotten”);
- carry his/her data, meaning can ask the managed data articulated, widely used, and readable form for transferring them to another organization; and
- protest against the management of his/her data.

5 Authority with right of surveillance in connection with data management

Hungarian National Authority for Data Protection and Freedom of Information (NAIH)

Hungary, 1125 Budapest, Szilágyi Erzsébet fasor 22/c.

Present regulation of CE Certiso Kft. is published on its website.

Modifications

Version, date	Modification	Explanation
v01, 2020.03.20	Initial edition.	CE Certiso Kft. has been designated as the notified body for conducting conformity assessment under MDR (Regulation (EU) 2017/745 on medical devices).