

Declaration of Consent and Collection Notice

regarding the processing of Personal Information via the Health Data Platform operated by Carl Zeiss Sdn. Bhd. Axis Business Campus, Unit G.02, Block B, No.13 & 13A, Jalan 51A/225, Seksyen 51A, 46100, Petaling Jaya, Selangor, Malaysia ("ZEISS")

As part of the medical treatment, your healthcare provider processes your Personal Information in line with data privacy regulations and shares them with organizations strictly in support of that process. ZEISS is one of those organizations and provides your healthcare provider with cloud-based services, which support them in the diagnosis and process of your treatment as well as allowing them to collaborate and consult with other healthcare providers and you concerning your healthcare program.

ZEISS would like to access your data to improve the services provided and contribute to medical research by developing improved methods for diagnosing and managing diseases (secondary use of data). In this constellation ZEISS takes over the responsibility for the data processing. The processing of your data for secondary use will be done in a way that cannot identify you or your data directly. A detailed list of the secondary use cases can be found below.

This document consists of the declaration of consent as well as of the data privacy notice, which details what data will be processed in which manner by ZEISS, your rights as a data subject and how to exercise those rights. Should you choose not to allow ZEISS to use your data for these secondary purposes, **your medical treatment at your healthcare provider will not be affected in any way.**

1. Declaration of Consent

In alignment with the Collection Notice above, and to enable the continuous improvement of medical treatments that can be enabled by insights that are generated out of multiple datasets compliant with local privacy law regulations, we require your consent.

This consent form

- provides information about how ZEISS as the respective responsible entity (data controller) processes your Personal Information, and
- serves as basis for the corresponding consent needed from you to authorize such processing.

DECLARATION OF CONSENT

Yes, I voluntarily consent to the pseudonymization (removal of all attributes which would directly identify me such as name, ID, address, telephone number) of my Personal Information, especially including biometric and health-related data (e.g., anamnesis data, diagnostic data and treatment data like surgery planning, surgery report, surgery videos, outcome data), by ZEISS by means of the HDP and the subsequent use of the pseudonymous data for the below-mentioned purposes:

- a) for **research purposes** by ZEISS, and its affiliates such as Carl ZEISS Meditec AG, Carl ZEISS AG and Carl Zeiss Vision GmbH such as determining whether there are certain risk factors for complications (e.g. pre-existing conditions such as high blood pressure, allergies, medical history such as other family members also had the condition, etc.) or whether certain treatments have been particularly successful; this research serves as basis for **further** improvement of medical treatments.
- b) in order **to enable research by third-party researchers** vetted by ZEISS (e.g., university professors, and other medical scientists) or **pharmaceutical companies, biotechs and medtechs** who conduct research on new treatments and have entered collaboration agreements with ZEISS. The transferred data are relatively anonymous for these third-party researchers. This means, that the consent embraces the anonymization of Personal Information and their transfer afterwards.
- c) for **product improvement** and product development such as Artificial Intelligence (AI) algorithms for diagnosing diseases based on the results of the research as well as **for the confirmation of related clinical or marketing claims** such as an AI algorithm that can reliably detect a disease in over 95% of the patients who have the disease.
- d) for **gathering health market intelligence** (e.g., information on actual trends regarding products, diagnosis and treatments such as analyzing whether the number of patients diagnosed with glaucoma is increasing and how fast) and **practice intelligence** (e.g., the frequency with which different products and/or services are used in different markets such as how many patients with cataract your healthcare provider treats compared to other healthcare providers) or for **supply chain planning** (e.g., planning of the quantities of cataract implants needed by a healthcare provider).

I understand that the personal information collected, held and processed by Zeiss will be destroyed and/or de-identified when it is no longer needed for one of the purposes described above.

I may withdraw my consent at any time with future effect (e.g., by email to hq@optimax.com.my) who will inform ZEISS about your decision without any negative consequences. For further details we refer to the attached Privacy Notice as provided by ZEISS. I have been granted sufficient time for consideration and all my questions have been answered to my satisfaction.

2. Privacy Notice

This Privacy Notice informs you about the types of your Personal Information and the purposes for which ZEISS processes your Personal Information, with whom it may be shared and which rights you have under the Malaysian Personal Data Protection Act 2010, EU General Data Protection Regulation (GDPR) as well as other applicable personal data protection laws and regulations.

2.1 Data collection:

The types of Personal Information collected by ZEISS are:

- Patient master data such as name, ID, address, age, gender, ethnicity, occupation, insurance, which your healthcare provider has entered into the IT systems.
- Biometric and health-related data such as anamnesis data, diagnostic data and treatment data like surgery planning, surgery report, surgery videos, outcome data, which your healthcare professional collects during your medical treatment.

2.2 Data processing:

The data processing for secondary use includes

- **Research by ZEISS and its affiliates:** examples of research may include determining whether there are certain risk factors for complications (pre-existing conditions such as high blood pressure, allergies, medical history such as other family members also had the condition, etc.) or whether certain treatments have been particularly successful. This research serves as the basis for further improvement of medical treatments in the future (e.g., for the calculation of the optimal lens power or for the selection criteria of patients for minimally invasive glaucoma surgery).
- **Research by 3rd party researchers or pharmaceutical companies, biotech or medtech:** researchers vetted by ZEISS or companies who have entered collaboration agreements with ZEISS, are able to pool their collective data and so create more effective data sets on which to conduct research (same use cases as in research by ZEISS). The data is effectively anonymous for these parties.
- **Product improvement and development:** the products include devices such as OCT scanners or

microscopes, as well as digital products such as Artificial Intelligence (AI) algorithms for diagnosing diseases or software applications to optimally plan a cataract surgery. The data can be based on the results of the research or on technical information relating to the frequency of errors when operating the devices or using the digital products. The use case also includes the identification of new products or services based on unmet needs such as the insight that the existing treatments are not effective for a certain patient population such as children or elderly patients. This also includes the use of data for the confirmation of clinical and marketing claims, by ZEISS, e.g. to conduct studies to demonstrate superiority/non-inferiority of ZEISS products or back up a claim that an AI algorithm that can reliably detect a disease in over 95% of the patients who have the disease.

- Gathering **market intelligence** such as information on actual trends regarding products, diagnosis and treatments such as analyzing whether the number of patients diagnosed with glaucoma is increasing in a country or region and how fast and **practice intelligence** such as the frequency with which different products and/or services are used in different markets such as how many patients with cataract your healthcare provider treats compared to other healthcare providers in the region. This allows ZEISS to determine the situation of the global market and detect regional characteristics. Lastly, improving **supply chain planning**: The data may be used for planning of the quantities of cataract implants needed by a healthcare provider and so ensure that stock levels are always at an optimal level.

2.3 Legal basis for the data processing:

The legal basis for processing your data is mainly based on your consent according to Section 6 and Section 9 of PDPA as well as ZEISS' or a third party's legitimate interest according to Section 6 subsection (2) (c) PDPA.

Your consent is entirely voluntary. If you do not wish to consent, or if at a later time you wish to withdraw your consent, you will not suffer any negative consequences. You can withdraw your consent with effect for individual purposes only or entirely by contacting ZEISS. Your withdrawal of consent only applies to the future use of your data, and ZEISS will cease using your data for such purposes to which your withdrawal pertains and delete your data if it is not required to be retained according to section 2.6. Your consent remains valid for a period of ten years unless you withdraw your consent at an earlier

point in time. This means that during this ten years-period, ZEISS may collect further data without you having to grant a new consent. If you return to your healthcare professional after ten years, you might be asked to give your consent again. The use of data already collected during the ten years-period remains permissible beyond this period and your data will be deleted as described in section 2.6.

2.4 Risks and Benefits for Patients

ZEISS does not intend to identify you based on the secondary use of your data (as described above under section 2.2). However, whenever medical data is collected and processed, there remains a residual risk that despite comprehensive technical and organizational protection measures such data can be traced back to you through additional information, e.g. by using publicly available information from the internet or social media. Should your data be accessed by unauthorized persons, this could lead to discriminatory or other potentially harmful use of your data.

Medical research has benefits to society as it aims to improve ZEISS' understanding of the cause of diseases and diagnosis and, on this basis, to improve prevention, care and treatment. However, you cannot personally expect any direct commercial or health benefit or advantage from the use of your data as described in this Privacy Notice. Your consent will have no impact on your current medical treatment.

2.5 Recipients of the data:

ZEISS only shares your pseudonymous data with third parties if you have given your express consent to it in section 1 or with service providers which are necessary for the operation of services (such as Carl ZEISS AG, Microsoft Deutschland GmbH, etc.).

Provided that this is permitted under applicable data privacy laws, your Personal Information, including medical data, might be transferred to recipients outside of the European Economic area, including India. We will take reasonable steps to ensure that your Personal Information is treated securely and in accordance with the requirements of the GDPR, including ensuring that a data transfer agreement is in place with the recipient in the form approved by the European Commission (so-called Standard Contract Clauses), where required.

ZEISS will **NOT** sell raw data that contains your individual dataset.

2.6 Retention of the data:

Your Personal Information will be retained for as long as necessary to fulfil the purposes for which the data was collected as described in section 2.2 above. If you revoke your consent, your pseudonymous data will no longer be used for any future secondary use thereafter.

When we have no ongoing legitimate business need to process your personal information, we will delete such information, or, if this is not possible (for example, because your personal data has been stored in backup archives for audit purposes), then we will securely store your personal data and isolate it from any further processing until deletion is possible.

For detailed information about your ability to access personal information we hold, or making any inquiries related to your rights, or any questions regarding this privacy notice or how ZEISS uses your Personal Information, please contact your HCP via **hq@optimax.com.my**, who will collaborate with ZEISS to address your request. The HCP is the only entity which can fully identify you and thus ensure that your request is handled correctly.

Contact:

Carl Zeiss Sdn. Bhd.

Axis Business Campus, Unit G.02, Block B,
No.13 & 13A, Jalan 51A/225, Seksyen 51A,
46100, Petaling Jaya, Selangor, Malaysia

E-mail: info.meditec@zeiss.com

Website: <https://www.zeiss.com/meditec-ag/home.html>

If you have a data privacy concern, please contact:

Corporate Data Protection Officer

Carl-Zeiss-Strasse 22

73447 Oberkochen

Contact via email (no confidential content, please)
dataprivacy@zeiss.com: