Valid from 01. August 2026

Special Terms and Conditions
Medical device

1 Introduction

1.1 General

The "Special Terms and Conditions: Medical device" of HCI Solutions Ltd («HCI»). shall apply to the customer in addition to the contract, including any annexes, other Special Terms and Conditions and the General Terms and Conditions (GTC). In the event of contradictions between individual components of the contract, the following order shall apply: i) individual contract, ii) annexes to the individual contract, iii) Special Terms and Conditions and iv) the GTC.

1.2 Definition of terms

Contract
A "Contract" within the meaning of these GTC is concluded when the customer/user accepts an offer from HCI. These GTC shall form an integral part of the Contract, unless expressly agreed otherwise in writing in the Contract.

HCI-Services
If the term "HCI-Services" is used, this refers to the offer in Section 2 of the GTC.

Customers
The term "Customer" is used in connection with entities who use HCI-Services. In particular – but not exclusively – these include system providers, platform providers, hospitals, and pharmacies.

User
The term "User" is used in connection with entities who make use of HCI-Services on the basis of a Contract with a Customer. In particular – but not exclusively – these include service providers and patients.

2 Use of web- and application-based services as a medical device

2.1 Distributor within the meaning of the law

As soon as the Customer puts HCI-Services (in the sense of medical devices, e.g. Documedis CDS.CE) into operation, it is to be regarded as a "Distributor" in accordance with Art. 4 para. 1 letter i of the Medical Devices Ordinance (MedDO). It is therefore responsible for fulfilling the regulatory requirements and obligations of a Distributor in accordance with the Medical Devices Ordinance. In particular, this includes the reporting of serious incidents pursuant to Art. 54 MedDO in conjunction with Art. 14 para. 5 MDR and the provision of information to authorities pursuant to Art. 54 MedDO in conjunction with Art. 14 para. 6 MDR.

2.2 Responsibility of the Customer

The Customer bears exclusive responsibility for integrating the web services and applications provided by HCI. Any change to the presentation, API and APP results or icons constitutes a change to the medical device and is the sole responsibility of the Customer. In such cases, the Customer, as the manufacturer, shall be responsible for the proper quality and conformity of this medical device within the framework of the statutory provisions. As the manufacturer, the Customer is therefore responsible for the proper quality and conformity of this medical device within the framework of the statutory provisions.

2.3 Acceptance of the implementation of medical devices

HCI-Services offered as medical devices are subject to the Medical Devices Ordinance (MedDO). The integration of the medical devices (e.g. Documedis CDS.CE) into the primary software must be approved by the specialists from HCI using a standard test protocol before being deployed in productive use for the first time. This is based on the integration specification and test protocol of the device in question as defined by HCI. The testing must be carried out in good time before the software goes live for the first time. HCI will not activate the access authorisations for the respective service package on the Customer's side without prior acceptance. The Customer must disclose the integration and describe it in the acceptance document. It is the Customer's responsibility to initiate contact as part of the acceptance process. Until the time of this acceptance, HCI expressly disclaims any liability for the responses issued in the Customer's system to queries submitted to the services.

2.4 Release management

The acceptance document describes the integration of a medical device (e.g. Documedis CDS.CE) into the Customer's software. If the Customer makes its own release, it is responsible for carrying out the test cases described in this document again in order to ensure the integration can continue to be used without error. If errors or changes to a medical device (e.g. Documedis CDS.CE) arise as a result of a Customer release, the Customer must inform HCI immediately.
When integrating new medical devices, HCI must be informed of the activation of the new HCI-Services and

acceptance must be carried out again as a joint operation and logged using the acceptance document.
If HCI makes adjustments to the acceptance document that have an impact on the test cases described in the document, the test cases must be carried out again and logged as a joint operation. HCI will take the initiative in this situation.

3 Customer's obligations to cooperate and responsibilities

3.1 Obligation to update

To remain usable, the HCI-Services must be updated regularly by the Customer and User. HCI reserves the right to discontinue updating obsolete systems (such as Documedis 2018-01) after a certain period of time and to shut them down with a notice period of six months. HCI reserves the right to switch off older interfaces earlier, especially if this must be done for security reasons. Notification of this will be sent out via the HCI website and/or via release notes and/or via e-mail. The Customer undertakes to ensure that the joint Users can adopt the updated versions of the HCI-Services provided by HCI in their respective software in a timely, periodic, manual or automatic manner. The Customer can also be instructed by the User to perform the update for them.

3.2 Compliance with procedures and specifications

The Customer must observe the relevant processes in relation to HCI and comply with the technical and content-related specifications of HCI in accordance with the information relating to the various HCI-Services available on the HCI website, e.g. user manuals. In particular, the master data and services provided by HCI must be implemented correctly in the software in terms of content and science.

3.3 Customer's obligations to provide information

The Customer shall inform HCI on an ongoing basis and without being asked to do so:
a) of changes to its own company as well as changes to joint Users via email to sales@hcisolutions.ch
b) of the occurrence of safety-critical errors in the HCI-Services within 24 hours, in particular – but not exclusively – if HCI-Services which are medical devices (e.g. Documedis CDS.CE) are concerned, the provisions of Section 2.1 apply

3.4 Quality assurance agreement

In the event that a quality assurance agreement has been concluded between the Parties, the Customers – within the meaning of the law, the "Distributor" – are obliged to contact the "manufacturer" – within the meaning of the law – or HCI immediately in the event of a reportable incident in accordance with the quality assurance agreement.

3.5 Changes to HCI-Services by the Customer

The Customer shall be solely responsible for the software products into which it integrates the HCI-Services and for any reformatting, restructuring and additions to these products and/or changes to their content and/or their assignments and/or allocations resulting from the processing of the HCI-Services carried out by it itself or by third parties on its behalf. The Customer shall also be responsible for any incomplete or incorrect transfer of the HCI-Services from one software product to another or to other systems. The Customer is therefore obliged to indemnify HCI in full against all third-party claims caused by such reformatting, restructuring, additions and/or changes to the content of the service packages or defects in the integration of the HCI-Services into the software products used by the Customer or the defective transfer of HCI-Services from one software product to another or to other systems or defects in the software products themselves, including any lawyer's and court costs.
The Customer is also obliged to include a disclaimer in its software and documentation that is recognisable to Users, stating that the Customer is liable for any errors, defects and damage caused by integration, reformatting or other technical changes to the master data provided by HCI, but that the User is liable for all decisions made on the basis of the data provided.

3.6 Non-compliance with the Customer's obligations to cooperate / responsibilities

Failure by the Customer to comply with its obligations to cooperate and responsibilities in terms of deadlines or quality may lead to delays, errors, disruptions and additional work (e.g. due to the need to repeat work). HCI is entitled to invoice the Customer for additional work and additional costs it incurs due to a lack of or insufficient cooperation on the part of the Customer or due to incorrect information or instructions by the Customer at HCI' current fee rates. HCI shall be released from all liability and warranty in connection with the non-fulfilment of the Customer's obligations to cooperate and responsibilities in terms of deadlines and/or quality.