

## *General Terms and Conditions for Software (Lifetime, on-premises)*

### **1. Scope**

- 1.1 These General Terms and Conditions (hereinafter referred to as "GTC") shall apply to all License Agreements between Nihon Kohden (hereinafter referred to as "NK") and the contracting party (hereinafter referred to as the "Distributor"), collectively referred to as the "Parties", insofar as they concern the provision of Software as a lifetime license and the Software is operated under the on-premises model within the IT Infrastructure of the Distributor's End-Customer.
- 1.2 The Distributor's terms and conditions shall not apply, even if NK does not expressly object to their validity in individual cases. The Distributor's terms and conditions shall only apply if NK expressly accepts them on a case-by-case basis.
- 1.3 The contract between the Parties comprises the following documents, which, in the event of any conflict, shall take precedence in the following order:
  - 1.3.1 License Agreement;
  - 1.3.2 Annexes to the License Agreement;
  - 1.3.3 these Terms and Conditions.

### **2. Definitions**

- 2.1 Software refers to all programs in machine-readable form. The term "Software" does not include content or data that is processed by the Software.
- 2.2 License Agreement refers to the contractual agreement between NK and the Distributor regarding the specific obligations and rights of both parties. The License Agreement shall be concluded through offer and acceptance.
- 2.3 End-Customer refers to the legal entity or natural person who purchases the license from the Distributor.
- 2.4 Manufacturer refers to the legal entity that developed the Software.
- 2.5 Lifetime License refers to the granting of a permanent, i.e. time-unlimited, right to the Distributor to provide the Software to their End-Customers for use in the contractually agreed version, in accordance with the terms of the Lifetime-License purchase.
- 2.6 On-premises model refers to a licensing model in which the Distributor operates the Software independently of NK on their own IT Infrastructure.
- 2.7 Software Update refers to updates to the Software, which may include security updates, patches, bug fixes or upgrades.
- 2.8 Patch or bug fix refers to Software Updates designed to correct defects in the Software.
- 2.9 Upgrade refers to Software Updates that include new features, improved usability or enhanced integration capabilities. They go beyond patches and bug fixes and may include, for example, additional modules, new interfaces, optimised workflows or user interface improvements.
- 2.10 Object Code refers to the machine-readable, executable form of the Software, which is generated by compiling the Source Code and can be executed directly by a computer.

- 2.11 Source Code refers to the human-readable form of the Software written in a programming language, which serves as the basis for creating the Object Code.
- 2.12 IT Infrastructure refers to all technical infrastructure provided and operated by the End-Customer, including hardware (servers, storage systems, network components, etc.), operating systems, databases and other system components on which the Software is installed and operated.
- 2.13 Intended use (of the Software) refers to the use of the Software exclusively for the purpose described in the user manual and in the manner specified in the documentation, in compliance with the technical requirements and contractual agreements.
- 2.14 Confidential information means any information that (1) is expressly marked or designated by a party as confidential or secret, or labelled as confidential in some other way; (2) is clearly intended to be treated as confidential under the circumstances; or (3) is protected by statutory confidentiality provisions.

### **3. Provision and use of the Software; copyright and usage rights**

- 3.1 NK shall grant the Distributor the non-exclusive right to provide the Software in Object Code to their End-Customers for intended use, in the scope and version agreed upon in the License Agreement. The specific features, functionality and intended purpose of the Software are set forth in the user manual.
- 3.2 NK reserves the right to engage third parties to provide their services.
- 3.3 The Distributor shall acquire the Software as a Lifetime License. This Lifetime License entitles the Distributor to use the contractually agreed version of the Software for an unlimited period of time. Software Updates are not automatically included in the Lifetime License and can be contractually agreed upon separately by the Distributor if desired.
- 3.4 The Software shall be subject to the Manufacturer's copyright. All rights to the Software, documentation and other materials provided by NK shall remain exclusively with NK or their licensors. The Distributor shall only be granted the rights of use expressly stipulated in the License Agreement and these GTC. The Distributor shall not acquire any rights whatsoever to the Software's Source Code. All rights not expressly granted shall remain with NK.
- 3.5 NK shall grant the Distributor the non-exclusive right to provide the Software to their End-Customers for intended use to the extent contractually agreed and in accordance with the applicable terms and conditions. The Distributor is not permitted to use the Software for any purpose or in any manner other than that stipulated in the Agreement.
- 3.6 The Distributor's rights of use shall be limited exclusively to:
  - 3.6.1. the installation of the Software on an IT-Infrastructure operated by the End-Customer;
  - 3.6.2. the execution of the Software for the purposes described in the user manual;
  - 3.6.3. the creation of backup copies of the Software, to the extent necessary for its intended use and for data backup;
  - 3.6.4. the duplication and modification of the Software within the End-Customer's IT-Infrastructure, to the extent that this is strictly necessary for the intended use of the Software, including error correction.
- 3.7 Furthermore, the Distributor is not authorised to:

- 3.7.1. reproduce the Software in whole or in part;
  - 3.7.2. translate, modify, arrange, or otherwise alter the Software;
  - 3.7.3. decompile or reverse engineer the Software, unless permitted by mandatory legal requirements;
  - 3.7.4. distribute, publicly disclose, or make the Software publicly available, unless NK has given prior written consent in each individual case.
- 3.8 The quantitative scope of the Lifetime License is set forth in the License Agreement.
- 3.9 The documentation pertaining to the Software that NK provides to the Distributor is set forth in the License Agreement. Unless otherwise agreed in the License Agreement, the following shall apply:
- 3.9.1. the user manual describing the functionalities and the intended use of the Software;
  - 3.9.2. other technical documentation required for the intended configuration and use of the Software.
- 3.10 The documentation shall be provided in English. NK is entitled to provide the documentation in electronic form (e.g. PDF). The Distributor is not entitled to reproduce, distribute or make the documentation available to third parties, unless this is necessary for the contractual use of the Software by the End-Customer.

#### **4. Installation**

- 4.1 The Distributor shall ensure that the End-Customer's IT IS meets the technical requirements specified in the user manual.
- 4.2 The Distributor shall install and perform the initial configuration of the Software on the End-Customer's IT Infrastructure in accordance with the terms of the License Agreement.
- 4.3 NK shall provide the Distributor with the installation files, and the Distributor shall perform the installation at the End-Customer's premises in accordance with NK's instructions.

#### **5. Software Updates, Upgrades**

- 5.1 NK shall provide the Distributor with upgrades to the extent that this service has been expressly agreed upon in the License Agreement or otherwise.
- 5.2 NK shall provide the Distributor with agreed-upon Software Updates or upgrades available as follows:
  - 5.2.1. NK shall notify the Distributor of the availability of Software Updates or upgrades;
  - 5.2.2. NK shall provide available Software Updates or upgrades to the Distributor. The Distributor shall then independently install the Software Updates or Upgrades on the End-Customer's system.
- 5.3 Upon installation of a Software Update or Upgrade, the Distributor hereby acquires the same rights of use to the Software Update or Upgrade as to the original Software.

- 5.4 Simultaneous productive use of both the previous version of the Software and a Software Update or Upgrade is only permitted if this has been expressly agreed in writing by NK and the Distributor.

## **6. Distributor's obligations and cooperation**

- 6.1 The Distributor shall handle communication between NK and the End-Customer, as necessary. NK shall not be liable for any delays on the part of the Distributor.
- 6.2 The Distributor may only make the Software available to their End-Customers after providing them with the corresponding end-customer agreements. If the Distributor resells or leases the Software to their End-Customers, they shall notify NK of the name and address of each End-Customer, as well as any subsequent changes.
- 6.3 The Distributor shall ensure that any use of the Software by their End-Customers is always in accordance with these GTC. The Distributor shall be liable for the actions and omissions of their End-Customers with respect to the Software to the same extent as for their own conduct.
- 6.4 The Distributor shall be responsible for providing appropriate and ongoing training, at their own expense, to all of their employees who distribute the Software, provide related services or perform other activities related to the Software. The training must ensure that the employees concerned have sufficient knowledge of the Software to be able to present, distribute and support it professionally. The Distributor shall ensure that such training is regularly updated, especially in the event of Updates, new features, or changes to the Software.
- 6.5 The Distributor is obligated to provide its End-Customers with instructions for the correct operation and proper use of the Software. This includes, in particular, clear guidance regarding the End-Customer's IT Infrastructure in which the software is operated, its application, and any security-related or functionality-related requirements.
- 6.6 The Distributor shall provide users of the Software within their sales territory with appropriate customer service, including installation assistance, troubleshooting, provision of Updates or patches, and other support services necessary for the proper use of the Software, regardless of whether the Software was purchased through the Distributor or not.
- 6.7 The Distributor shall provide NK with all information, data and documents necessary for the performance of all services in a timely, complete, and accurate manner. NK has no obligation to investigate the information provided. NK is entitled to rely on the accuracy and completeness of the information, data and documents provided by the Distributor. NK shall not be liable for defects, delays or impossibility of performance that are attributable to incomplete, incorrect, or late information, data or documents provided by the Distributor or their End-Customers.
- 6.8 The Distributor shall designate contact persons to NK who are authorised to:
- 6.8.1. issue instructions and make decisions regarding the provision of services;
  - 6.8.2. report defects or malfunctions.
- 6.9 The Distributor is obligated to inform NK immediately of any significant developments that may affect the provision of services.

- 6.10 The Distributor shall fulfil their cooperation obligations in their own interest and may not claim any compensation for doing so. If the Distributor fails to fulfil their obligations to cooperate, or fails to do so in a timely or proper manner, the Distributor shall be in default of their obligations to cooperate, even without a reminder from NK.
- 6.11 If it has been agreed that services shall be provided on-site at the End-Customer's premises, the Distributor shall ensure that the End-Customer grants NK's employees access to the premises and IT Infrastructure on the agreed dates, to the extent necessary for the provision of the contractual services.

## **7. Special provisions for medical devices**

- 7.1 The following requirements (including those of the MDR and the German Medical Devices Enforcement Act) have been fulfilled by NK before market launch and must be verified by the Distributor:
- 7.1.1 Issuance of the EU Declaration of Conformity for the Software;
  - 7.1.2 CE marking of the Software;
  - 7.1.3 Availability of all relevant information that must be provided with the Software;
  - 7.1.4 In the case of imported software, fulfilment of the importer's corresponding requirements;
  - 7.1.5 Assignment of a Unique Device Identifier by the Manufacturer, if applicable.
  - 7.1.6 When verifying 7.1.1, 7.1.2, 7.1.3 and 7.1.5, the Distributor may use a sampling procedure that is representative of the PRODUCTS.
- 7.2 The Distributor is required to maintain written records of (a) the name and address of each End-Customer to whom the Distributor has sold Software, as well as the model, serial or batch numbers and delivery dates, (b) all service and maintenance work performed by the Distributor on all medical devices, including the model and serial numbers, the date of repair, and the issue being corrected; and (c) all End-Customer complaints relating to the medical devices, including information about incidents or potential incidents involving the misuse or repeated misuse of medical devices by users. At the request of NK and upon the expiration or termination of this undertaking—if and to the extent required for post-market surveillance purposes—the DISTRIBUTOR shall provide copies of these documents. This provision shall remain in effect even after the termination or expiration of this undertaking.
- 7.3 In the event that a recall or corrective action, including a Field Safety Corrective Action (FSCA), for Software (collectively referred to as a "Recall") is reported to the relevant regulatory authorities, the Parties shall cooperate in connection with the Recall. As a general rule, NK shall carry out the Recall and modify the Software.
- 7.4 Upon request by the relevant authority, the Distributor shall provide such authority with all information and documentation available to it that is necessary to demonstrate the conformity of the product in question. The Distributor shall be deemed to have complied with this obligation if it provides NK or their authorised representative for the product in question with the necessary information. Upon request by the relevant authority, the Distributor shall provide samples of the product in question free of charge or, if this is not possible, grant access to the goods. NK shall reimburse the Distributor for the necessary Software and/or expenses incurred in this regard.

## **8. Warranty**

- 8.1 NK warrants that the Software shall conform to the agreed specifications upon delivery and be suitable for its intended use. NK further warrants that no third-party rights shall be infringed in connection with the provision of the contractual services. The information provided in the user manual shall be the sole authoritative source for the Software's specifications.
- 8.2 Public statements, promotional claims or advertisements by NK do not constitute a guarantee of any specifications, unless they have been expressly agreed upon in writing.
- 8.3 Before reporting a defect, the Distributor must first check within their own area of responsibility to determine the cause of the defect. In particular, this includes:
  - 8.3.1. Verifying whether the End-Customer's IT Infrastructure meets the minimum technical requirements;
  - 8.3.2. Verifying whether the defect was caused by modifications made by the End-Customer or by third-party systems;
  - 8.3.3. Verifying whether the Software is being used in accordance with its intended purpose.
- 8.4 Notifications of defects must be submitted in writing.
- 8.5 If an investigation determines that no defect actually exists, the Distributor shall bear the costs incurred by NK for defect investigation measures.
- 8.6 In the event of a defect, NK has the right and the obligation to remedy the defect or re-perform the affected contractual service, at its discretion, within a reasonable period during NK's normal business hours. The remedy method (repair or replacement) selected is at NK's sole discretion.
- 8.7 NK may remedy defects at its own discretion by:
  - 8.7.1. Providing patches, bug fixes or an updated version of the Software that corrects the defect;
  - 8.7.2. Providing a defect-free version of the Software; or
  - 8.7.3. Providing a non-identical but equivalent solution that does not restrict, or only insignificantly restricts, the contractually agreed use of the Software by the End-Customer, insofar as this is reasonable for the End-Customer.
- 8.8 If the Software infringes the rights of third parties and third parties assert their rights, thereby preventing the Distributor from using the Software for its intended purpose or restricting such use, NK shall, within a reasonable period of time and at its own discretion, take appropriate measures to remedy the defect of title:
  - 8.8.1. Acquire the necessary rights from the third party in question so that the Distributor can use the Software without infringement;
  - 8.8.2. Modify the Software in such a way that the rights of third parties are no longer infringed, without significantly impairing the intended use of the Software; or
  - 8.8.3. Provide a legally compliant, equivalent replacement solution that does not infringe the rights of third parties, provided that this does not restrict, or only insignificantly restricts, the End-Customer's ability to use the Software for its intended purpose, and that this is reasonable for the End-Customer.
- 8.9

- 8.10 The Distributor is obligated to grant NK the time and opportunity necessary for remedying the defect and to provide the necessary cooperation. The place of performance for NK's remedy obligations is the place of performance for the contractual services.
- 8.11 In the event of defects, NK has the right to two attempts at remedying the defect before the remedy is deemed to have failed. The remedy is only deemed to have definitively failed if:
- 8.11.1. NK seriously and definitively refuses to remedy the defect;
  - 8.11.2. the remedy is unreasonable for the Distributor ;
  - 8.11.3. the remedy would entail disproportionate costs for NK.
- 8.12 In the event that the final attempt at remedying the defect fails, the Distributor is entitled to the following warranty rights:
- 8.12.1. Reduction of the fee; or
  - 8.12.2. Withdrawal from the contract, provided the defect is not minor.
- 8.13 Warranty claims by the Distributor are excluded in the following cases:
- 8.13.1. Software malfunctions resulting from improper use, modifications to the Software by the Distributor, End-Customers or third parties, inadequate IT Infrastructure or failure to follow the instructions and documentation provided;
  - 8.13.2. Incompatibilities of the software with hardware or Software not listed as compatible in the technical documentation.
- 8.14 The Distributor's warranty claims shall expire 12 months after the Software is made available. The limitation period does not restart if subsequent performance is made or repairs are carried out as part of a remedy.
- 8.15 11.16 Notwithstanding the foregoing, the Distributor's warranty claims shall expire within two (2) years from the statutory commencement of the limitation period, or for claims for damages based on intent or gross negligence, injury to life, limb or health, or liability under mandatory product liability regulations pursuant to Directive (EU) 2024/2853, as well as in cases of fraudulent concealment.
- 8.16 The foregoing provisions shall apply mutatis mutandis to any Software Updates or Upgrades.

## **9. Liability**

- 9.1 Claims for damages and reimbursement of expenses by the Distributor against NK (hereinafter referred to as "Claims for Damages"), regardless of the legal basis, in particular due to breaches of duty arising from the contractual relationship, tort, culpa in contrahendo, delay or impossibility of performance, are excluded.
- 9.2 The foregoing limitation of liability shall not apply in the event of:
- 9.2.1. claims for reimbursement of expenses in connection with subsequent performance;
  - 9.2.2. liability claims under mandatory product liability regulations pursuant to Directive (EU) 2024/2853;
  - 9.2.3. intent or gross negligence on the part of NK, their legal representatives or vicarious agents;

- 9.2.4. culpable injury to life, limb or health; or
  - 9.2.5. a culpable breach of an essential contractual obligation (cardinal obligation), i.e. a obligation whose fulfilment is essential for the proper performance of the contract and on whose compliance the Distributor regularly relies and is entitled to rely.
- 9.3 NK's liability for breach of an essential contractual obligation is limited to compensation for foreseeable damages typical of this type of contract, unless the breach was intentional or grossly negligent; or liability arises from injury to life, limb or health; or liability arises under mandatory product liability regulations pursuant to Directive (EU) 2024/2853.
- 9.4 Except in cases of intent or gross negligence on the part of NK, and in cases of damages resulting from injury to life, limb or health, NK shall not be liable for lost profits; indirect or consequential damages, in particular production losses and business interruptions, and damages that could have been avoided by the Distributor performing complete and proper data backups.
- 9.5 NK shall not be liable if the basis for liability is attributable to a breach of duty by the Distributor.
- 9.6 Where NK's liability is excluded or limited, this shall also apply to the personal liability of NK's employees, agents, legal representatives and vicarious agents.
- 9.7 If third parties assert claims against NK for infringement of their rights caused by a breach of duty by the Distributor, their employees, legal representatives, executive bodies or vicarious agents, or third parties commissioned by the Distributor, the Distributor shall indemnify NK against all such claims. This indemnification shall also cover NK's legal defence costs, including reasonable attorneys' fees and court costs. This shall not apply if the Distributor proves that they are not responsible for the breach of duty.
- 9.8 Claims for damages by the Distributor shall become time-barred 12 months from the commencement of the statutory limitation period; however, the foregoing shall not apply in the cases outlined in sections **Error! Reference source not found.**, **Error! Reference source not found.** and **Error! Reference source not found.** of these GTC.
- 9.9 Any further claims by the Distributor are excluded, unless otherwise stipulated in the contract.

## **10. Fees, payment**

- 10.1 The Distributor is obligated to pay the fees agreed upon in the License Agreement, plus the applicable statutory value-added tax.
- 10.2 For NK services requested by the Distributor that are not listed in the License Agreement, the Distributor may request a current price list. NK shall then provide this to the Distributor.
- 10.3 If a fee based on hourly work has been agreed upon, NK shall submit a formal expenses statement to the Distributor at the end of an agreed billing period, detailing the actual expenses incurred. The Distributor must review the expenses statement within five (5) calendar days of receipt and raise any objections in writing. If no objection is received within this period, the expenses statement shall be deemed approved.
- 10.4 NK is entitled to demand reasonable advance payments from the Distributor where more extensive contractual services are required.

- 10.5 For payments due, NK shall send the Distributor a verifiable invoice to the billing address provided by the Distributor, taking into account any advance payments made by the Distributor. The invoiced amount is payable without deduction within the period specified in the invoice by bank transfer to a bank account designated by NK. The payment receipt date shall be the date on which the payment is credited to NK's bank account. All payments shall be made in euros (EUR) unless another currency has been expressly agreed upon. Place of fulfilment for payments is NK's registered office.
- 10.6 If payment deadlines are not met, the Distributor shall automatically be in default, even without a receiving payment reminder from NK. In the event of default, NK may charge default interest at a rate of 9 percentage points above the current base interest rate and a reasonable reminder fee. Further claims by NK remain unaffected.

## **11. Confidentiality, data protection**

- 11.1 If no separate confidentiality agreement has been concluded between the Parties, they shall nevertheless maintain strict confidentiality regarding all confidential information that comes to their knowledge in the course of their business relationship, in particular trade or business secrets.
- 11.2 The parties are obligated to keep secret all confidential information, in particular:
- 11.2.1. Not to pass on or disclose confidential information to third parties;
  - 11.2.2. Not to use or exploit confidential information for any purpose other than those contractually agreed upon;
  - 11.2.3. Not to duplicate, copy or reproduce confidential information; or
  - 11.2.4. Not to reverse engineer, decompile or otherwise analyse confidential information;
  - 11.2.5. unless this is necessary in a specific case for the fulfilment of the Agreement; and
  - 11.2.6. to implement appropriate technical and organisational measures to protect confidential information against unauthorised access, loss, destruction or disclosure.
- 11.3 Disclosure of confidential information is only permitted to the extent necessary for the fulfilment of the Agreement (need-to-know principle). In cases of doubt, the Parties shall, prior to disclosing any information to third parties, seek guidance from the other party as to whether such information is to be considered confidential. The Parties shall only grant access to confidential information to employees or representatives who are bound by professional secrecy or who have previously been subject to confidentiality obligations consistent with those set forth in these GTC, which also obligate them to maintain confidentiality to the extent legally permissible under labour law, even after their departure from the company.
- 11.4 The following confidential information is exempt from these obligations:
- 11.4.1 Information that was demonstrably already known to the recipient at the time of conclusion of the License Agreement or subsequently becomes known to them from a third party without violating any confidentiality agreement, statutory provisions, or governmental regulations;

- 11.4.2 Information that is publicly known at the time of conclusion of the License Agreement or subsequently becomes publicly known, provided this is not due to a breach of these GTC; or
  - 11.4.3 Information that must be disclosed due to legal obligations or by order of a court or authority. In such cases, the recipient obligated to disclose information shall notify the other party in advance, to the extent permissible and possible, and give them the opportunity to take action against the disclosure.
- 11.5 Both parties shall comply with all applicable legal data protection requirements regarding the processing of personal data in connection with the fulfilment of this Agreement.

## **12. Governing law, jurisdiction**

- 12.1 The law of the country where NK is headquartered shall apply, to the exclusion of the the UN Convention on Contracts for the International Sale of Goods.
- 12.2 The sole place of jurisdiction for all disputes arising from the contractual relationship between NK and the Distributor, including international disputes, shall be the court with jurisdiction over NK's registered office. This Agreement on the place of jurisdiction applies only if the Distributor is a merchant, a legal entity under public law or a special fund under public law. However, NK is also entitled to bring legal action against the Distributor at the place of fulfilment or at the Distributor's general place of jurisdiction.

## **13. Final provisions**

- 13.1 The place of fulfilment for all contractual services provided by NK is NK's registered office, unless otherwise expressly agreed.
- 13.2 Any transfer of contractual rights or obligations by the Distributor requires the prior written consent of NK to be deemed valid. If the Distributor assigns their claim against NK without NK's consent, the assignment shall nevertheless be effective. In this case, NK may, at its own discretion, effect payment to either to the Distributor or to the third party to discharge their obligations.
- 13.3 The Distributor is only entitled to set off claims if their counterclaim has been legally established, is undisputed, or has been acknowledged in writing by NK.
- 13.4 The Distributor is only entitled to exercise a right of retention if their counterclaim is based on the same contractual relationship and has been legally established, is undisputed, or has been acknowledged in writing by NK.
- 13.5 Amendments or supplements to the License Agreement must be in electronic form to be effective. This also applies to the amendment or cancellation of this form requirement itself.
- 13.6 Unless otherwise stipulated in the License Agreement or these GTC, contractual notices and declarations must be made in writing.

Should any provision of these GTC be or become void, invalid or unenforceable for any legal reason, the validity of the remaining provisions shall not be affected. The Parties shall replace the void, invalid or unenforceable provision with a valid provision that comes closest to the economic purpose of the original provision.