SERVICE AGREEMENT

concluded by and between:

Czech Republic – State Institute for Drug Control, an organisational unit of the state

Organisation Reg. No. (IČ): 00023817

Registered office: Šrobárova 48, 100 41, Prague 10

Represented by: Mgr. Irena Storová, MHA, Director

Bank details: account no. 623101/0710 (kept by ČNB)

(hereinafter referred to as the "**Contract Giver**")

and

LORENZ Archiv-Systeme GmbH

Company Reg. No. (IČ): 045 238 242 18

VAT Reg. No. (DIČ): DE114182772

Registered office: Eschborner Landstr. 75, 60489 Frankfurt, Germany

Represented by: XXX   CEO

Bank details, account no.: XXX

(hereinafter referred to as the "**Provider"**)

(the Contract Giver and the Provider being further collectively referred to also as the "**Contracting Parties**")

On the below specified day, month and year, the Contracting Parties concluded this Service Agreement (hereinafter referred to also only as the "**Agreement**"):

Preamble

The Contract Giver, as a contracting authority opened a procurement procedure no. VZ05/2021 for public contract "eCTD tool maintenance and support in SÚKL", in which the tender submitted by the Provider was evaluated as the most optimal one, and for this reason, the Contract Giver hereby concludes this Service Agreement with the Provider:

Article 1.

Subject-matter and purpose of the Agreement

1.1 On the basis of this Agreement, the Provider undertakes to provide the Contract Giver with services constituting of the support and maintenance of the tool for work with documentation in the eCTD and NeeS format (hereinafter referred to as the "Application SW") procured through the Contract Giver´s licence agreement file no. 68/2016 of 29

April 2016, concluded on the basis of the outcome of procurement procedure VZ52/2015 "Implementation of the eCTD tool in SÚKL", and do so for an indefinite period of time since the coming into effect of this Agreement. The services shall be provided in the following scope:

(a) Provision of technical support and maintenance of the manufacturer (hereinafter referred to as "maintenance") for the Application SW within the scope defined below:

1x docuBridge Basic server licence: for use both in testing and production environments;

The server licence includes:
- docuBridge Import module for all types/formats of submissions,
- docuBridge Display module for submissions (Navigation, Annotation, Hyperlinks, Print),
- docuBridge Search module,
- docuBridge Administrative module,
- dB Invoker licence for the creation/use of links/references,
- 1x LORENZ eValidator OEM version

170x docuBridge user licences for the displaying and processing of marketing authorisation dossiers in the production and testing environments

The below specified licences are included in the aforementioned licence counts:
- 15x for document uploads,
- 20x for technical validation.

The maintenance services for the aforementioned licences include, *inter alia*, Application SW bug fixes, provision of new upgraded releases of the Application SW and patches and updates of eCTD and NeeS technical validation criteria. A more detailed maintenance service specification is provided under Annex 1 hereto.

(b) Provision of Helpdesk services for service support of Application SW operation, which will be provided for the Contract Giver in the 5x9 regimen, i.e., on working days from 8:00 a.m. until 5:00 p.m.

(c) Elimination of reported defects specified in greater detail under Art. 2 and within the timelines stipulated by Art. 2 hereof.

The performance defined under this paragraph 1.01 is further in the Agreement referred to as the "**Service**" or "**Services**".

1.2 The Contract Giver undertakes to pay the agreed price for the Services provided hereunder to the Provider.

1.3 The purpose of this Agreement is to safeguard a fully operational condition of the Application SW, necessary for the fulfilment of the Contract Giver´s statutory powers.

Article 2.

Elimination of defects and Service availability

2.1 The services encompass the Provider´s obligation to eliminate defects of the Application SW and to safeguard its prescribed availability, as specified by this Article.

2.2 A critical (category A) defect, i.e., an emergency, shall mean non-functionality of the Application SW as a whole or an outage of a part of the Application SW hindering its operation. In respect of such defects, the Provider undertakes to commence the works to eliminate the defect within 4 working hours of the moment of provable detection of the defect by the Provider, or of the moment when this defect was provably reported by the Contract Giver´s authorised person in writing, via e-mail or Helpdesk application. The Provider undertakes to eliminate such defect within 3 working days of the commencement of the works aimed at the elimination of the defect. This provision shall be effective unless agreed otherwise with a view to the nature of the defect, provably by means of a written agreement by and between the authorised persons of the Contract Giver and of the Provider.

2.3 A moderate (category B) defect shall mean a defect causing non-functionality of a part of the Application SW which is not a category A defect, but consists of a defect that significantly restricts the functional use of the Application SW for purposes for which the SW is intended. In respect of these defects, the Provider undertakes to commence works to eliminate the defect no later than on the working day following the moment the Provider provably detected the defect or following the moment the defect was provably reported by the Contract Giver´s authorised person in writing, via e-mail or Helpdesk application. The Provider undertakes to eliminate such defect within 5 working days of the commencement of the works aimed at the elimination of the defect. This provision shall be effective unless agreed otherwise with a view to the nature of the defect, provably by means of a written agreement by and between the authorised persons of the Contract Giver and of the Provider.

2.4 A minor (category C) defect shall mean a limited functionality of the Application SW or behaviour of the Application SW which is not a category A or B defect. In respect of these defects, the Provider undetrtakes to commence works o eliminate the defect no later than within 2 working days of the moment the Provider provably detected the defect or of the moment the defect was provably reported by the Contract Giver´s authorised person in writing, via e-mail or Helpdesk application. The Provider undertakes to eliminate such defect within 10 working days of the commencement of the works aimed at the elimination of the defect. This provision shall be effective unless agreed otherwise with a view to the nature of the defect, in a provable manner by means of a written arrangement agreed by the authorised persons of the Contract Giver and of the Provider.

2.5 Where the defect is reported outside Helpdesk working hours, the commencement of works to eliminate the defect and the timeline for defect elimination as per paragraphs 2.02 to 2.04 hereof shall begin only upon the next start of Helpdesk working hours.

2.6 The Provider undertakes to safeguard monthly availability of the Application SW referred to under Art. 1.01(a) hereof at the minimum level of 95 %. Application SW availability shall be evaluated for each calendar month. For this purpose, the percentage monthly system availability shall be established using the following formula:

$$D\_m = (T\_ok - T\_err)/T\_ok * 100$$

where:

D_m is the monthly percentage (%) availability of the Application SW;

T_err is the total time of unavailability in the monitored period;

T_ok is the total time for which availability was monitored or also the time of Service operation.

The monitored period shall mean the time from 8:0 a.m. until 5:00 p.m. on each working day of the respective calendar month.

Application SW shall be considered unavailable in those cases when it exhibits a category A or B defect.

The unavailability time shall mean the time from the moment of the provable detection of the defect by the Provider or the moment the defect was provably reported by the Contract Giver´s authorised person in a manner stipulated hereby (hereinafter referred to as the "report"), until the unavailability is eliminated.

The unavailability time shall not include Application SW unavailability caused by a defect provably outside the scope of this Agreement (e.g., a hardware or network infrastructure or operating system defect, recovery time, etc.).

Furthermore, the unavailability time shall not include the time of a force majeure defect occurring independently of the Provider´s will and preventing the Provider to fulfil its obligations, unless it may be reasonably expected that the Provider would divert such obstacle or its consequences or could foresee such obstacle at the time the obligation was assumed. The unavailability time shall not include time necessary for the conduct of scheduled maintenance works of the Provider. The unavailability time shall not include time for which the Contract Giver does not allow access to the Provider´s employees for the purposes of eliminating the defect, either.

Article 3.

Provider´s rights and obligations

3.1 The Provider shall provide the Services referred to hereunder at its own liability and shall safeguard any and all economic, material and human resources in a manner allowing for the fulfilment of the purpose of this Agreement.

3.2 For the duration of Service provision hereunder, the Provider undertakes to provide these Services in the highest quality attainable, to exercise due professional care, taking account of the Contract Giver´s interests.

3.3 The Provider undertakes to observe the Contract Giver´s instructions. The Provider shall be obliged to forthwith notify the Contract Giver of any and all circumstances detected by the former in the performance of this Agreement that could affect the provision of Services hereunder or the issuance of the Contract Giver´s instructions or amendments thereto. The Provider shall always notify the Contract Giver of possible inadequacy of the latter´s instructions; should the Contract Giver insist on meeting its instructions despite the Provider´s notification, the Provider shall, to the extent appropriate, bear no liability for potential defects in the performance arising provably from the execution of such inappropriate instructions.

3.4 The Provider undertakes to provide, without unnecessary delay, the Contract Giver with a list of persons who shall be involved in the provision of Services hereunder, including both the Provider´s staff.The list shall be executed for the purposes of providing access to the Contract Giver´s premises. The list shall give the person´s name and surname and their employer (or contractor, where employment relationship is not concerned). The Provider shall be obliged to hand this list of persons over to the Contract Giver with an explicit written consent of these persons with the processing of their personal data by the Contract Giver for the purposes of allowing their access to the Contract Giver´s premises and allowing access to the relevant parts of the Contract Giver´s information system. In case of a breach of this obligation, the Provider shall be fully liable under the Act on Personal Data Protection. The Contract Giver undertakes to process these personal data solely for the purposes of Service execution and in compliance with Act No 101/2000 Coll., on Personal Data Protection and Amendment to Some Acts, as amended (hereinafter referred to also as the "ZOOÚ"), until the consent is withdrawn in writing. The provider shall be obliged to agree on the specific working hours and hours

of movement of persons providing the Services hereunder at the Contract Giver´s premises with the Contract Giver in advance, of which a written record endorsed with the signatures of the authorised persons shall be executed. In case of any personnel changes, the Provider shall be obliged to forthwith provide the updated list of persons to the Contract Giver.

3.5 The Provider undertakes to submit to the Contract Giver a completed and signed request for access to the Contract Giver's information system (e.g., servers, parts of infrastructure) for persons who will be involved in the provision of Services hereunder immediately upon the conclusion of this Agreement. Should, within the term hereof, the Provider request a change to the persons accessing the information systems of the Contract Giver, the former shall be always obliged to submit a request for information system access termination for the person(s) whose access rights are to be cancelled, and at the same time, submit a new request for access to the information system for person(s) who are to be newly given access rights. When submitting the requests for termination/initiation of access to the Contract Giver´s information system, the Provider shall be obliged to use a form provided under Annex 2 hereto. The Contract Giver shall assess the request no later than within two working days of its delivery. In the assessment process, the Contract Giver may request more information on the purpose of request issuance. A copy of the approved or declined request shall be handed over by the Contract Giver to the Provider. Regarding access to the Contract Giver´s information system, the Provider shall be, moreover, obliged to observe the following obligations:

- The Provider shall be obliged to ensure and throughout the term hereof shall be liable to the Contract Giver for the fact that the relevant parts of the Contract Giver´s information system are actually accessed only by those persons for whom a request for access to the information system was submitted and granted by the Contract Giver's Information Security Manager (hereinafter referred to as the "MBI"). The Contract Giver shall be entitled to check, at any time, what persons actually access the relevant part of the Contract Giver´s information system and in such a case, the Provider shall be always obliged to provide and evidence such information to the Contract Giver. A breach of this obligation by the Provider shall be considered a substantial breach of the Provider´s contractual obligations.

- The granted access rights may be used solely by the person for whom the request was granted by the MBI. The former must not disclose the granted access rights to any other person. A breach of this obligation shall be considered a substantial breach of the Provider´s contractual obligations.

- Upon termination of a working relationship between a person who has been granted access rights and the Provider or its subcontractor, the Provider shall be obliged to request termination of access to the Contract Giver´s information system for this person, and do so no later than within two working days of the moment of the operative event occurring. The Provider shall be obliged to assume the same course of action in case the reason or need for the relevant person of the Provider or its subcontractor to access the Contract Giver´s information system ceases to exist. A breach of this obligation shall be considered a substantial breach of the Provider´s contractual obligations.

3.6 The Provider shall be obliged to attend meetings summoned by the Contract Giver to discuss the provision of Services hereunder. Unless specified otherwise, such meetings shall be always attended by the authorised persons of the Provider referred to under paragraph 15.01 hereof.

3.7 In the performance hereof, the Provider undertakes to cooperate with any experts or other professionals appointed by the Contract Giver, so as to achieve the purpose hereof.

3.8 The provider confirms that as of the date of signature hereof it has concluded an insurance contract covering liability for damages caused by its business operation for the minimum amount of 5,000,000 CZK (in words: five million Czech crowns), with a maximum 10% co-payment, and that it shall maintain validity of this contract for the term hereof and for the minimum of 6 months of termination of activities hereunder. Upon a Contract Giver´s request, the Provider shall be obliged to present the insurance contract or insurance certificate of the respective insurance company.

3.9 In the provision of Services hereunder, the Provider undertakes to observe any necessary measures to prevent any possible material damage to the Contract Giver or damage to the health of the Contract Giver´s employees.

Article 4.

Contract Giver´s rights and obligations

4.1 The Contract Giver shall be obliged to provide the Provider with complete, true, and straightforward information that is absolutely necessary for the provision of Services hereunder, and do so in a timely manner, unless the nature of such information implies that the information should be secured by the Provider itself as part of its performance of the subject-matter of this Agreement.

4.2 The Contract Giver shall be obliged to create proper conditions for the provision of Services hereunder by the Provider and to cooperate with the latter for the term hereof as necessary, if the Provider requests such cooperation on reasonable grounds. This particularly applies to the hand-over of documents and other information essential for the provision of Services, provision of access to the Contract Giver´s premises. The Provider´s request for cooperation must be made in writing, addressed to the Contract Giver´s authorised person as referred to under paragraph 15.01 hereof. The request must be submitted reasonably in advance so that the provision of the required cooperation may be reasonably/realistically expected with a view to the Contract Giver´s working hours and the scope of the required cooperation (e.g., the scope of required documentation or activity).

4.3 The Contract Giver shall be authorised to establish the times of Service provision in its premises reflecting its needs.

Article 5.

Price of the Services

5.1 The Contracting Parties have agreed that the price of the Services referred to under Art. 1 and 2 hereof that have been provided properly, in due time, and in compliance with the conditions hereof shall be 157,500,- CZK excl. VAT, i.e. 190,575,- CZK incl. VAT for each calendar quarter of Service provision. This price shall be the maximum acceptable price which cannot be exceeded and it shall cover any and all costs of the Provider associated with the Service provision within the scope referred to under Art. 1 hereof and Annex 1 hereto.

5.2 The price referred to under paragraph 5.01 has been set as a lump-sum amount.

5.3 Should a VAT rate change (i.e., an increase or decrease) occur during the term hereof (i.e. after the conclusion of the Agreement), the Provider shall be obliged to reflect this

change in its billing (invoicing) of the price of the Services, i.e. increase or decrease the price by the VAT change amount.

5.4 Where the Services are not provided for the full duration of the calendar quarter, the Provider shall be entitled to invoice only a pro-rata part of the price of Services for the calendar quarter in question, reflecting the number of days in the calendar quarter during which the Services were actually provided.

Article 6.

Invoicing and payment terms

6.1 The Contract Giver shall pay to the Provider the price established under paragraph 5.01 hereof on the basis of invoices issued by the Provider. The Services shall be invoiced on a quarterly basis, always as of the 15th day of the month following the calendar quarter for which the provision of Services is being invoiced.

6.2 The invoices must include all particulars of an accounting and VAT documents, as set forth by Act No 235/2004 Coll., on VAT, and Act No 563/1991 Coll., on Accounting, as amended. In case the submitted invoice does not contain the particulars required by the Act or by this Agreement, the Contract Giver shall be entitled to return it to the provider within the credit period, stating the reason for returning it. In such a case, a new credit period shall start on the date of the repeated delivery of the corrected invoice to the Contract Giver.

6.3 The invoice credit period shall be 30 days of invoice issuance, whereas the Provider shall be obliged to deliver the invoice to the Contract Giver within 3 working days of the date of issuance thereof. The invoice credit period shall begin on the date of provable delivery of a flawless invoice to the Contract Giver. The Contracting Parties have agreed that the obligation to pay the invoice shall be fulfilled on the day when the amount in question is sent from the Contract Giver´s account to the Provider´s account.

6.4 Should the Contract Giver be in default with payments hereunder, it shall be obliged to pay to the Provider default interest on the owing late payment in the amount stipulated by relevant legal regulations.

6.5 The Provider is aware of its own financial costs associated with the performance of the subject-matter of this Agreement and shall not request any other financial payments in the course of the Service provision above the scope of the agreed price and payment terms as referred to under Art. 6 hereof.

Article 7.

Place of performance

7.1 The Contracting Parties have agreed that the place of Service and activity performance hereunder shall be the Contract Giver's workplace located at the following address: Prague, Šrobárova 48, 100 41 Prague 10 and the Provider´s registered office.

7.2 The services and activities referred to hereunder may be also provided in a remate manner, via electronic communication networks (as referred to under Act No 127/2005 Coll., on Electronic Communication), if practicable with a view to the nature of the performance in question.

Article 8.

Subcontracting on the part of the Provider

8.01 The Provider shall be obliged to perform this Agreement exclusively via its own employees.

Article 9.

Protection of confidential information

9.1 The Provider shall be obliged to maintain confidentiality in respect of any and all facts learned in the performance of this Agreement that are not intended for publication by a legal regulation or are not commonly known. Furthermore, the Provider undertakes not to enable any person to disclose confidential information to unauthorised third parties, unless this Agreement stipulates otherwise. The information provided by the Contract Giver to the Provider or obtained by the Provider in association with the fulfilment of its obligations hereunder, shall be handled by the Provider as confidential information.

9.2 The following shall not be considered confidential information for the purposes of this Agreement:

(a) Information that has become publicly available through ways other than disclosure by the Provider;

(b) Information obtained by the Provider from sources other than the Contract Giver, that is labelled as public by their provider.

9.3 The Provider undertakes to use confidential information solely for the purposes of fulfilling its obligations arising herefrom. Furthermore, the Provider undertakes to ensure that neither it nor any other person acquainted with confidential information in compliance with this Agreement shall disclose it to any third party except for cases:

(a) concerning the provision of access to confidential information to persons for whom access to such information is necessary for the purposes of fulfilment of the Provider´s obligations arising herefrom (for subcontractors);

(b) concerning the provision of access to confidential information with the Contract Giver´s prior written approval;

(c) required by a binding legal regulation or where such obligation is stipulated by a final and legal decision of the concerned authority issued on the basis of the authority´s statutory power. The Provider shall be obliged to evidence such fact upon the Contract Giver´s request without any unnecessary delay.

9.4 The Provider also undertakes to ensure the protection of confidential information against unauthorised disclosure to third parties. Should the Provider reasonably suspect that confidential materials have been illegally disclosed (obtained), it shall be obliged to forthwith inform the Contract Giver to this effect.

9.5 The Provider shall be obliged to return to the Contract Giver any and all materials and objects received from the latter or on behalf of the latter during performance hereof without any unnecessary delay, after the termination of this Agreement. The Provider shall be obliged to remove confidential information stored in electronic format, no later than upon the expiry of its mandatory archival, if such statutory obligation applies to the provider.

9.6 The binding obligation to protect confidential information shall survive this Agreement.

9.7 The Provider undertakes to bind also any and all of its staff and subcontractors involved in the provision of Services for the Contract Giver with the Contract Giver´s approval, to maintain confidentiality, and shall do so without unnecessary delay.

9.8 The Contract Giver shall be authorised to publish this Agreement or parts thereof as well as information pertaining to its performance any time within the term hereof as well as after its expiry, and the Provider takes account of this and agrees with it.

Article 10.

Contractual fines

10.1 Should the Provider breach any obligation set forth under Art. 7 hereof, it shall be obliged to pay to the Contract Giver a contractual fine in the amount of 100,000,- CZK for each individual breach.

10.2 Should the Provider breach any obligation set forth under Art. 8 hereof, it shall be obliged to pay to the Contract Giver a contractual fine in the amount of 100,000,- CZK for each individual breach.

10.3 If the Provider fails to commence works to eliminate a critical defect or to resolve a critical defect in due time as referred to under 2.02 hereof, the Provider shall pay to the Contract Giver a contractual fine in the amount of 5,000,- CZK for each started hour (in case of commencement) or for each started working day (in case of elimination) in default from the timelines stipulated under paragraph 2.02 hereof.

10.4 If the Provider fails to commence works to eliminate a moderate defect or to resolve a moderate defect in due time as referred to under 2.03 hereof, the Provider shall pay to the Contract Giver a contractual fine in the amount of 3,000,- CZK for each started working day in default from the timelines stipulated under paragraph 2.03 hereof.

10.5 If the Provider fails to commence works to eliminate a minor defect or to resolve a minor defect in due time as referred to under 2.04 hereof, the Provider shall pay to the Contract Giver a contractual fine in the amount of 1,000,- CZK for each started working day in default from the timelines stipulated under paragraph 2.04 hereof.

10.6 Should the Provider fail to perform the subject-matter of this Agreement while the contractual relationship lasts, the Provider shall be obliged to pay to the Contract Giver a contractual fine in the amount adequate to the pro-rata portion of the price for Service provision as referred to under Art. 5 hereof for each day in default from the performance of the subject-matter of this Agreement. Such default shall constitute a substantial breach of the Provider's obligations.

10.7 The payment of the contractual fine shall not release the Provider from its obligation to perform for the Contract Giver as agreed hereunder or from the obligation to compensate any damage, if applicable, including compensation in amounts exceeding the amount of the contractual fine.

Article 11.

Contract term

11.1 This Agreement is concluded for an indefinite period of time.

11.2 This Agreement shall expire prior to the expiry of its term as referred to in the paragraph above, for the following reasons:

a) By notice or withdrawal from the Agreement;

b) Loss of authorisation to operate in a manner necessary for the provision of Services on the part of the Provider;

c) By written agreement of the Contracting Parties.

11.3 In case of termination of the Agreement, any and all arrangements agreed by the contracting Parties regarding the Provider´s liability for damage, entitlement to contractual fine, and protection of confidential information shall survive the Agreement.

Article 12.

Notice and withdrawal from the Agreement

12.1 Either Contracting Party can terminate the Agreement in full or parts of it. The Contract Giver shall be authorised to terminate the Agreement without giving any reason, the notice period for the Contract Giver being 3 months and starting on the day immediately following the date of the provable delivery of the notice to the other Contracting Party. The Provider shall be authorised to terminate the Agreement only due to the Contract Giver being in default from the payment of the invoice issued by the Provider after the performance hereof, i.e., after proper and timely provision of the Services in compliance with this Agreement; the default on the part of the Contract Giver must last for more than 60 days. The notice period for the Provider shall be 6 months and shall start on the day immediately following the date of the provable delivery of the notice to the other Contracting Party. A proper delivery of the notice shall mean its delivery via a postal service provider, a courier, or its delivery to the data mailbox of the other Contracting Party.

12.2 Having received the notice referred to in the previous paragraph, the Provider shall be obliged to continue its activities hereunder until the expiry of the notice period, unless it receives another written instruction from the Contract Giver. At the same time, the provider shall be obliged to notify the Contract Giver of measures necessary to prevent any damages for the Contract Giver that might arise from failure to complete a particular activity.

12.3 Either Contracting Party shall be authorised to withdraw from this Agreement without unnecessary delay in case the other Contracting Party substantially breaches this Agreement as referred to under Section 2002 of the Civil Code.

12.4 Either Contracting Party shall be obliged to notify the other Contracting Party of the former´s withdrawal from the Agreement by means of a written notice of withdrawal. Such notice must clearly identify what the withdrawing Contracting Party considers to be the substantial breach of the Agreement, including reference to the specific breached contractual obligation.

12.5 Withdrawal from the Agreement shall take effect upon the delivery of the written notice of withdrawal to the other Contracting Party, unless a deferred effect of the withdrawal is implied by the content of the notice of withdrawal. A proper delivery of the notice of withdrawal from the Agreement is considered to be its delivery by a postal service provider, a courier, or its delivery to the data mailbox of the other Contracting Party.

12.6 Withdrawal from the Agreement shall be without prejudice to the provisions concerning the protection of information, dispute settlement, secured claims of either of the contracting Parties, compensation for damage, and the provisions concerning such rights and obligations the nature of which implies their survival after the withdrawal from the Agreement (this concerns, in particular, the obligation to provide monetary payments for performance provided prior to the withdrawal from the Agreement).

Article 13.

Force majeure

13.1 The Contracting Parties shall not be liable for partial or complete failure to fulfil the contractual obligations due to force majeure circumstances. Force majeure shall be considered such circumstances that arise after the signature of this Agreement as a result of inevitable events of exceptional nature that directly affect the performance of the subject-matter of the Agreement and that could not have been foreseen by the Contracting Party relying on the existence of the influence (force) prior to the conclusion of this Agreement and that is completely beyond the control of the concerned Contracting Party regardless of the effort exercised thereby.

13.2 Where force majeure circumstances arise, the timelines for the fulfilment of the contractual obligations shall be extended by the time of effect of the force.

13.3 The Contracting Party affected by force majeure shall be obliged to notify the other Contracting Party in writing about the start and end of the force majeure event and do so forthwith, no later, however, than within fifteen (15) days. Should the former fail to do so, it cannot effectively rely on the force majeure effects.

Article 14.

Severability provision

If any of the provisions hereof is or becomes ineffective or unenforceable, other provisions of this Agreement shall remain valid and effective. In place of the invalid, ineffective or unenforceable provision, the provisions of generally binding legal regulations governing issues of mutual relationship between contracting parties shall be applied. The Contracting Parties then undertake to regulate their relationship by adopting another provision which, in effect, will best reflect the intention of the invalid or ineffective or unenforceable provision. Should any provision that would otherwise be adequate in terms of completeness of the regulation of the rights and obligations be missing from this Agreement, the Contracting Parties shall exert maximum effort to add such provision into this Agreement.

Article 15.

Final provisions

The authorised persons of the Contracting Parties appointed for the purposes of negotiations regarding performance hereunder shall be the following individuals:

For the Contract Giver
XXX

For the Provider:
XXX
Provider´s telephone number for reporting of defects: XXX

Provider ´s e-mail for reporting of defects: Support@lorenz.cc

The Provider undertakes to inform its authorised persons for negotiations regarding performance hereunder immediately after the conclusion of this Agreement about the processing of their personal data within the scope of this paragraph by the Contract Giver for the purposes of performance hereunder throughout the term of the Agreement.

15.1 The following annexes form an integral part of this Agreement:

Annex 1:   Licence conditions of the Application SW manufacturer for the provision of maintenance

Annex 2:   Request form for initiation/termination of access to the Contract Giver´s information system

15.2 This Agreement may be amended solely in writing, by means of numbered and bilaterally endorsed arrangements, explicitly called "Amendment to the Agreement". No other records, protocols, etc. shall be considered amendments to the Agreement.

15.3 If the Provider creates any copyright work as part of the provision of the Services hereunder, as referred to by Act No 121/2000 Coll., the copyright Act, as amended, the Provider, through this Agreement provides the Contract Giver with unexclusive authorisation, unlimited in time, to execute the right of use of such copyright work for the purposes of proper operation of the Application SW. Remuneration for the provision of the licence referred to by the previous sentence forms part of the price under paragraph 5.01 hereof. This paragraph shall become effective upon the handover of the copyright work by the Provider to the Contract Giver.

15.4 Should either Contracting Party encounter circumstances preventing the proper performance hereof, it shall be obliged to notify the other Contracting Party to this effect without unnecessary delay.

15.5 This Agreement is executed in 2 counterparts of which each of the Contracting Parties shall receive one.

15.6 The Contracting Parties declare that they have carefully read the Agreement and that its content is clear and comprehensible to them. They declare that this Agreement has not been concluded in distress or under conditions otherwise unfavourable for either Contracting Party.

15.7 Any cases which are not addressed by the provisions hereof, shall be governed by the relevant provisions of the Civil Code or other effective legal regulations of the Czech Republic.

15.8 The Provider takes account of the obligation to publish the Agreement in the Register of Contracts (hereinafter referred to as the "Register of Contracts") as required by Act No 340/2015 Coll., on Register of Contracts, and by signing this Agreement it expresses its consent with the disclosure of all data stated in the Agreement by the Contract Giver in the Register of Contracts established by the aforementioned Act, except for personal data.

15.9 This Agreement shall come into force on the date of its signature by both Contracting Parties and shall take effect on the date of its publication in the Register of Contracts.

In witness of the Agreement being the expression of their true, serious and free will, the undersigned, being duly authorised to conclude the Agreement for the Contracting Parties, have attached their handwritten signatures.

Done in Prague on 30.11.2021   Done in Frankfurt on 5.11.2021

Contract Giver: Provider:
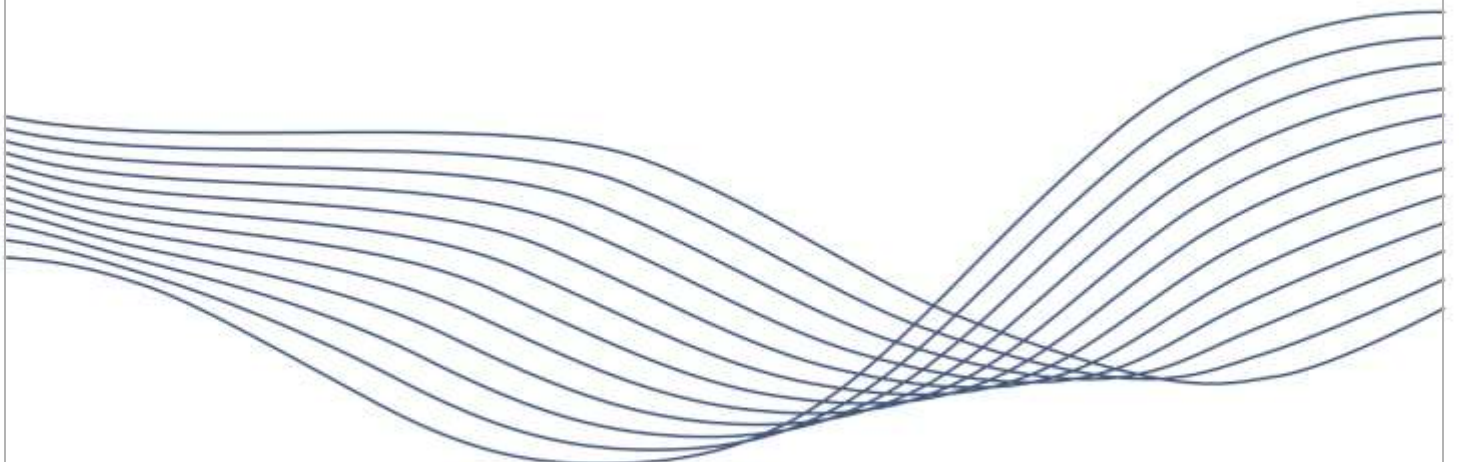State Institute for Drug Control   LORENZ Archiv-Systeme GmbH

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Mgr. Irena Storová, MHA   XXX
State Institute for Drug Control,   LORENZ Archiv-Systeme GmbH
Director   CEO

Release and Support Services

FIVE Standard

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LORENZ Release and Support Services (FIVE Standard) - service through Annual Software Maintenance

LORENZ (or a LORENZ Certified Partner) shall provide Release and Support Services (RSS) (FIVE Standard) (as defined herein) to the Customer, per the terms of this Agreement (the "Agreement") and as set forth at the LORENZ Support Services Website, at http://www.lorenz.cc/support/. The applicable LORENZ (or a LORENZ Certified Partner) entity, Effective Date, and Software will be set forth on the applicable license agreement, Customer's purchase order, or, if Customer has purchased support on a per-incident basis, in the registration form completed by Customer upon such purchase (collectively the "Order").

1. Definitions

In this Agreement the following terms shall have the following meanings (unless the context requires otherwise):

Customer Responsibility:

Customer Responsibility means in this context that the customer agrees to co-operate with LORENZ in any manner necessary for LORENZ to fulfill its obligations with regards to Release and Support Services. The Customer shall in particular take the necessary measures to define and document Incidents to an extent which can be reasonably expected from the Customer. In particular, the Customer shall document any Incident related phenomena, monitor the systems and hardware environment closely and generate reports (all of the foregoing in detailed form in writing by using the LORENZ incident report forms and other materials (collectively, the Incident Support Material) and shall use the support portal provided by LORENZ. The Incident Support Material may include systems printouts, input and output data, interim and test results and additional comments, if necessary, or other appropriate documentation to illustrate the Incident if requested by LORENZ. The Customer grants LORENZ Employees commissioned with hotline-support access to the computers on which the Software is saved and/or loaded. The Customer acknowledges that proper communication of any Incident Support Material is a prerequisite for LORENZ efficient correction activities.

Defect:

Defect means a reproducible malfunction of the Standard Software that has clearly been identified as a malfunction attributed directly to the Standard Software (and not the environment or incorrect usage) and is replicable in LORENZ' environments.

Effective Date:

Effective Date means the date from which RSS (FIVE Standard) are provided to the Customer as set forth on the applicable license agreement, Customer's purchase order, or, if Customer has purchased support on a per-incident basis, in the registration form completed by Customer upon such purchase.

Incident:

Incident means an event related to the supported SOFTWARE reported by customer.

Incident Support Material:

Incident Support Material means information customer has to submit when reporting an INCIDENT. Information to be provided, but are not limited to: (i) LORENZ Product Version; (ii) system (Production, Test system) affected by the INCIDENT, (iii) step-by-step description about actions have been done when the INCIDENT occurs; (iv) screenshots; (v) context and circumstances at the time the INCIDENT appeared; (vi) number of INCIDENT occurrences (once, frequently or continuously); (vii) log-files, configuration snapshot and the like, if applicable.

LORENZ ID:

LORENZ ID is a user specific access to LORENZ information, e.g. training certificates, userBridge documentation, video streams from LORENZ' various events, product documentation as well as product release sheets.

Product Release Support Period:

Product Release Support Period means the period for which RSS (FIVE Standard) supports product releases. Releases will be supported for a period of twenty-four (24) months after generally availability of the next Major Release. The Product Release Support Period includes the delivery of Minor and Specific Releases as well as services for the given time period.

Release Services (FIVE Standard):

Release Services (FIVE Standard) means the provision of Major Releases, Minor Releases and Specific Releases (each defined below), if any, to the Software, as well as corresponding documentation, to Customer.

- Major Release:
  Major Release means a generally available release of the Software that (i) contains functional enhancements and extensions, (ii) fixes for high severity and high priority bugs, and (iii) is designated by means of a change in the digit to the right of the decimal point (e.g. Software 18.1 to Software 18.2). Major Releases are usually released in April and October each year and are communicated via LORENZ ID.
- Minor Release:
  Minor Release means a generally available release of the SOFTWARE that (i) introduces a limited amount of new features, functionality and minor enhancements, (ii) fixes for high severity and high priority bugs, and (iii) is designated by means of a change in the digit to the right of the second decimal point (e.g. Software 18.1 to Software 18.1.1). Minor Releases are communicated via LORENZ ID.
- Specific Release:

Specific Release means a release which is (i) specific to a LORENZ Customer or to a technical environment, and (ii) is designated by means of a change in the digits to the right of the third decimal point (e.g. Software 18.1 to Software 18.1.0.01). Specific Releases are normally not communicated via LORENZ ID.

Response Time:

Response Time means the period between the receipt of the notice of an Incident and the beginning of the resolution of the Incident with a first status message to the Customer.

Service Period:

Service Period means the period for which RSS (FIVE Standard) have been agreed between LORENZ and Customer beginning at the Effective Date. Except as otherwise stated by LORENZ, RSS (FIVE Standard) are provided in Service Periods consisting of twelve (12) months.

Services Fees:

Service Fees means the fees for RSS (FIVE Standard) specified in a LORENZ invoice corresponding directly to the RSS (FIVE Standard).

Severity:

Severity is a measure of the relative impact a Defect has on the use of the Software, as defined by LORENZ, and is assigned by Customer when opening a support request provided that the Defect is reproducible by LORENZ. The following Severity levels apply:

- Severity 1:
  Severity 1 means a Defect that causes a complete loss of service. Normal business operations cannot be conducted, the Software function is mission critical and has a major impact on the business. The situation is an emergency with one or more of the following characteristics: (i) data is corrupted; (ii) critical function of Software solution is not available; (iii) unacceptable or indefinite delays for resources or response; or (iv) continual or arbitrary freeze or crash of the Software solution. Customers are requested to use this classification with great care, so that valid Severity 1 situations obtain the necessary resource allocation from LORENZ.

- Severity 2:
Severity 2 means a Defect that causes a severe loss of service (service degraded, disrupted or loss of critical functions). Normal business operations are severely impeded and there is a substantial impact on the business. There is no workaround available, however, operation can continue in a restricted fashion. Severity 2 Defects could include one or more of the following characteristics: (i) severe but intermittent Defects; (ii) loss of secondary or administrative functionality; or (iii) continual or repeated problems.

- Severity 3:
Severity 3 means a Defect for which there is a workaround available or that is less severe than Severity 1 or 2. Normal business operations are minimally impeded and there is a limited impact on the business. Severity 3 Defects could include one or more of the following characteristics: (i) user is able to use the Software solution but with some inconvenience; (ii) there is a non-critical system or service outage; or (iii) non-business critical system or service is degraded.

- Severity 4:
Severity 4 means a Defect that has no, no immediate, or low effect on the service or for which a reasonable workaround is readily available. Normal business operations are not yet impeded and there is low impact on the business. Severity 4 Defects could include one or more of the following characteristics: (i) the end user is still able to use Software solution; (ii) unavailability of non-critical services; or (iii) cosmetic changes, "nice to have" features, etc.

Software:

Software means Software offered on the LORENZ price list, and all the components shipped with the Software.

Support Services (FIVE Standard) cover assistance with technical, functional and validation questions and post-implementation product issues.

- A **Technical Support** service request is defined as assistance with one technical issue, problem or question relating to the use of a LORENZ product. Technical Support service requests shall not be used to substitute necessary product training or consulting. LORENZ retains the right to reject a request for that reason and offer consultancy or training instead.

- **Functional Support** service request is defined as assistance with one question relating to the product functionalities of a LORENZ product. Functional Support service requests shall not be used to substitute necessary product training or consulting. LORENZ retains the right to reject a request for that reason and offer consultancy or training instead.
- **A Validation Support** service request is defined as assistance with one question relating to a validation report created by LORENZ eValidator.

Support Services (FIVE Standard) do not cover the following:

- Service or assistance requests for implementation and configuration assistance, especially when customers do an upgrade or configuration on their own. Customer may request such additional services which will then be quoted separately. This also applies to Technical and Functional Support requests that are caused by an upgrade or a configuration which customers have done on their own.
- Development requests, including custom code development or support for third party systems.
- Database integrity or database performance issues, including tuning and optimization of the database.
- Network topology or environment issues.
- Application server issues not directly related to the LORENZ product implementation, configuration or operation.
- Other support service requests that are not covered by Technical, Functional and Validation Support as defined above.

Third Party Products:

Third Party Products means any software (in any form), hardware, supplies or service from or manufactured by a party other than LORENZ and is either (i) not delivered with the Software; or (ii) not incorporated into the Software.

2. Service Terms

2.1 Provision of Services

Subject to the terms of this Agreement, LORENZ shall, during the Service Period, provide Customer with RSS (FIVE Standard).

2.2 Service/Support Hours

LORENZ provides RSS (FIVE Standard) during its regular business hours as stated on http://www.lorenz.cc/businesshours. RSS (FIVE Standard) will not be rendered on statutory holidays as in effect at LORENZ' support location.

2.3 Response Time

The individual response time follows the schedule below:

Defect Severity as defined in I.	Response Time
1	Within 4 hours (Monday through Friday)
2	Within 1 Work Day
3	Within 2 Work Days
4	Within 5 Work Days

Table: Response Schedule

The target values as set forth in Table: Response Schedule above for Severity 1 (A category) and 2 Defects (B category) are only valid if:

- Severity of the Defect is undisputed and matching the Defect classification outlined in 1.
- Error is reproducible in LORENZ' environment
- LORENZ must have all requested information from the Customer relating to the suspected error.
- Time periods during which an error is registered at LORENZ in the Waiting for Customer Stage, will not be measured.

2.4 Escalation

The Customer shall have the right to escalate an unresolved software problem to LORENZ management levels, if the response times set forth in 2.3 are not complied with as described in the following Escalation Level Table.

Escalation Level	LORENZ
1	Manager Support
2	Director Development
3	CEO

Table: Escalation Levels

2.5 Purchase Requirements

Except as otherwise provided for by LORENZ, Customer may purchase initial RSS (FIVE Standard) only for the most current, generally available release of the Software, running unaltered on a designated system. Current LORENZ Software release information may be accessible via electronic media.

These Service Terms are subject to change at LORENZ' discretion and will automatically update to LORENZ' then-current Service Terms upon any renewal of RSS (FIVE Standard).

2.6 Exclusions

Services specifically excluded in the definition of Support Services (FIVE Standard), general advisory services as well as correction of Defects or problems, which are the result of Customer misuse, improper use, alteration or damage of the Software, caused by Third Party Products, unauthorized modifications, and equipment malfunction are not covered by the RSS (FIVE Standard) and shall be billed to Customer on a time and materials basis.

3. Services Fee Terms

3.1 Services Fees

Services Fees are due and payable on the Effective Date or, in the case of a renewal term, annually, but no later than the day of the commencement of the applicable Services Period as delineated on the Order Form and as adjusted at any time in the event Customer increases its Software licenses or usage.

In the event that Customer renews or adds a services offering, in relation to, e.g., an increase in Software licenses or usage that has a minimum term of one (1) year, Customer may elect to make services for all of its Software licenses coterminous with the renewed or added services. In such case, LORENZ will prorate the applicable Services Fees to extend the current Services Period to make it coterminous with such renewed or added services.

LORENZ has no obligation to provide RSS (FIVE Standard) until Customer is current on all Services Fees due and owing to LORENZ.

LORENZ reserves the right to increase its Services Fees to reflect increases in the general price level (i.e. inflation) from time to time.

3.2 Reinstatement Fees

For Software that is licensed on a perpetual basis, if a Customer purchases services after acquiring the Software licenses, or had elected not to renew services and later wishes to re-enroll in the services, Customer must move to the then-current Major Release of the Software and must pay a reinstatement fee including (i) the applicable Services Fees for the current Services Period; and (ii) the amount of Services Fees that would have been paid for the period of time that Customer had not enrolled in the services.

3.3 Incidental Expenses

For all on-site RSS (FIVE Standard), Customer shall reimburse LORENZ for reasonable travel and out of pocket expenses incurred.

4. Miscellaneous Terms

4.1   Limitation of Liability

IN NO EVENT SHALL LORENZ BE LIABLE FOR ANY INDIRECT, INCIDENTAL, SPECIAL OR CONSEQUENTIAL DAMAGES, OR DAMAGES FOR LOSS OF PROFITS, REVENUE, DATA OR USE, INCURRED BY CUSTOMER OR ANY THIRD PARTY, WHETHER IN AN ACTION IN CONTRACT OR TORT, EVEN IF LORENZ HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. LORENZ' LIABILITY FOR DAMAGES HEREUNDER SHALL IN NO EVENT EXCEED THE AMOUNT OF SERVICE FEES PAID BY CUSTOMER UNDER THIS RSS AGREEMENT.

Notwithstanding anything to the contrary in this RSS Agreement, LORENZ shall have no liability or responsibility with respect to claims or actions to the extent such claims or actions are: (i) caused or claimed to have been caused by Customer, including Customer's negligence; (ii) where the claim or action would not have occurred but for modification of the Software program (and/or associated software or services) by Customer or Customer's agent, or customization according to Customer's design; (iii) where the Software program (and/or associated software or services) are used in combination with equipment, software, or other products not supplied, required or recommended by LORENZ and such claim or action would not have occurred but for the combination; or (iv) Customer uses the Software program (and/or associated software or services) in a manner not provided by LORENZ and such claim or action would not have occurred but for Customer's use in that manner.

THE PROVISIONS OF THIS RSS AGREEMENT ALLOCATE THE RISKS BETWEEN LORENZ AND CUSTOMER. LORENZ' PRICING REFLECTS THIS ALLOCATION OF RISK AND THE LIMITATION OF LIABILITY SPECIFIED HEREIN.

4.2   Severability

If any provision of this Agreement is held to be invalid or unenforceable, the remaining provisions of this Agreement will remain in full force. Further, this provision 4.2 shall be considered enforceable.

4.3   Termination

Customer may terminate RSS (FIVE Standard) at any time by notifying LORENZ in writing at least thirty (30) days before the end of the pertinent Service Period. RSS (FIVE Standard) shall be terminated thirty (30) days after receipt of such notice.

LORENZ may suspend or terminate Customer's RSS (FIVE Standard) at any time if (i) Customer is in breach of its Software license restrictions, pursuant to Customer's Software

license; or (ii) Customer is in material breach of this Agreement, e.g., fails to pay the Services Fees.

Engineering
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LORENZ Life Sciences Group

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E-mail: posta@sukl.cz
Web: www.sukl.cz

…………………. Comp. Reg. No. (IČ): ………… (hereinafter referred to as the "Applicant") hereby requests provision of access to SÚKL servers

We hereby request that for our following employees:

....

....

access rights to the following servers be provided:

Server name		IP address

for the purposes of performance of agreement ……………. dated ……. /order ……………. dated …….

Accesses to servers may be used only for the specified purposes. The Applicant and their employees shall be obliged to protect the access rights against any unauthorised use or any misuse. Furthermore, they undertake to use the information they learn solely for the purpose for which they have been granted the access and shall refrain from further dissemination of the information.

The Applicant shall provide the access rights solely to their employees specified above who have been appointed to perform activities necessary for the fulfilment of the above-specified agreement/order. The Applicant undertakes to access only the servers applied for thereby and if the need for access ceases to exists, to inform SÚKL to this effect. The Applicant shall be obliged to inform SÚKL without

SÚKL

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any delay of the fact that an employee who has been granted access rights no longer performs activities for the Applicant for which the access rights have been granted thereto. Any transfer of access rights to another employee of the Applicant shall be subject to SÚKL´s prior approval for which the Applicant shall be obliged to apply using a new request.

Unauthorised use of access rights by the Applicant or their employee shall be considered breach of the granted permission with full responsibility for such breach as stipulated by effective legal regulations.

The Applicant and their employees accessing SÚKL servers undertake to observe any and all obligations stipulated in respect of personal data protection by relevant effective legal regulations, particularly 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) and Act No 127/2005 Coll., on Electronic Communications, and shall not allow any other person to gain and process such data. In case of a breach of personal data protection, the Applicant shall be obliged to forthwith inform SÚKL in writing by sending information about the incident to the following address: posta@sukl.cz. By signing this request, the Applicant certifies that their employees have been fully familiarised with the obligations stipulated by legal regulations referred to in the previous sentence and that the Applicant has obtained consent of the aforementioned employees with the provision of their personal data contained herein to SÚKL who shall record/process the data for the purposes of performance of the agreement/order.

The Applicant shall be responsible to SÚKL for any and all damage arising from the breach of the obligations stipulated hereby or by effective legal regulations committed by the Applicant or their employees. The Applicant shall be obliged to fully compensate any such damage to SÚKL.

Date: ……………………

……………………………………………
Signature

Approved by SÚKL´s Information Security Manager

Date: ……………………

……………………………………………
Signature