

(Translation from Czech)

SERVICE AGREEMENT

Entered into between:

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

Identification number: 00023817
Registered seat at: Šrobárova 48, ZIP: 100 41 Prague 10, Czech Republic
Represented by: PharmDr. Zdeněk Blahuta, director
Bank: 623101/0710 (opened with ČNB)
(hereinafter the **"Client"**)

and

Lorenz Archiv-Systeme GmbH

Identification number: 045 238 242 18
VAT No.: DE114182772
Registered seat at: Eschborner Landstr. 75, 60489 Frankfurt, Germany
Represented by: Wolfgang Witzel, President
Bank: account no.: IBAN: DE82503201910367909218, SWIFT: HYVEDEMM430
(hereinafter the **"Provider"**)

(the Client and the Provider jointly hereinafter as the **"Parties"**)

Have, on the below-specified day, month and year entered into this agreement regarding rendition of services (hereinafter also as the **"Agreement"**):

Preamble

The Client, acting as a contracting authority, has initiated a public procurement procedure no. VZ52/2015 "Implementation of eCTD tool in SIDC", in which the Provider's bid was evaluated as the most favorable. Therefore, the Client and the Provider, as the selected bidder, now enter into this Service Agreement:

Article 1

Scope and Purpose of Agreement

- 1.01 By this Agreement, the Provider undertakes to provide the Client, for the period of 4 years from the day of effect of this Agreement, services consisting of support, maintenance and development of tool for processing documents in eCTD and NeeS format (hereinafter the "Application Software") procured under License Agreement resulting from the public procurement procedure no. VZ52/2015 "Implementation of eCTD tool in SIDC". The services shall be rendered in the following scope:

- (a) Providing manufacturer technical support and maintenance (hereinafter the "Maintenance") regarding the Application Software in the following scope:

1x docuBridge Basic Server license: to be used for test and production system

Server license includes:

- *docuBridge Import module for eCTD and NeeS Submissions*
- *docuBridge View module for Submissions (Navigation, Annotation, Hyperlink, Print)*
- *docuBridge Search Module*
- *docuBridge Administrator Module*
- *dB Invoker license for Link creation/usage*
- *1x LORENZ eValidator OEM version*

170x docuBridge user licenses (named) for viewing and working with registration documents on production server

Following licenses are contained in this number:

- *15x for uploading documents*
- *20x for technical validation*

The Maintenance services in respect of the above-specified licenses shall include, among others, repairs of Application Software errors, providing new, improved versions of the Application Software and patches and updates of eCTD and NeeS technical validation criteria. The Maintenance services are specified in more detail in Appendix 1 hereof.

- (b) Help desk management for technical support of the operation of the Application Software provided to the Client in 5x9 regime, i.e. on business days from 08:00 AM to 05:00 PM CET.
- (c) Repair of reported defects as specified in Article 2 below by deadlines specified in Article 2 of this Agreement.
- (d) Services in the scope of 60 man-days (1 man-day shall mean 8 man-hours) throughout the entire duration of this Agreement, to be fulfilled based upon separate orders by the Client at a fixed rate for a man-hour as quoted in Article 5 hereof in the following scope:
- Application Software modifications according to the Client's requirements meaning especially (however not exclusively) individual modifications of the configuration of the Application Software or analysis and development of new functions of the Application Software,
 - providing consultations by the Provider's specialist regarding the use of the Application Software and implementation of training of new users.

The individual requirements regarding the services under this clause d) shall be implemented based upon separate orders by the Client confirmed by the Provider. The individual orders of the Client shall be sent by the authorized representative in technical matters in writing by e-mail or using the helpdesk application. The Provider shall then send the estimated scope of the services in expressed hours as well as delivery (hand-over) time from the e-mail address

of the Provider's authorized representative in technical matters to the e-mail address of the Client's authorized representative in technical matters. The client shall then, from the e-mail address of the Client's authorized representative in technical matters to the e-mail address of the Provider's authorized representative in technical matters, confirm the services within the scope of the given order, their scope in hours and the time of delivery (hand-over). From that point, the duty to fulfill the order shall be binding on both Parties. In case of any modifications of the Application Software, the result of any order can only be introduced to the production environment after the approval of the Client's authorized representative in technical matters. All results of fulfillment of any order shall be presented by the Provider to the Client for acceptance. A written acceptance certificate shall be drafted regarding such fact, to be signed by the authorized representatives of both Parties in technical matters, whereby the acceptance of the resulting implementation of the given order without any reservations shall be confirmed.

- 1.02 The Client shall pay the Provider the agreed price in consideration of the Services rendered under this Agreement.
- 1.03 The purpose of this Agreement is to secure a fully functional Application Software necessary to fulfill the statutory authority of the Client.

Article 2

Solving errors and Service availability

- 2.01 The Services paid by the fixed price under paragraph 5.01 clause a) hereof shall include the Provider's duty to remedy defects of the Application Software and ensure its prescribed availability as specified in this Article.
- 2.02 A critical error (category A) shall mean an emergency in the form of non-functioning of the Application Software as a whole or non-functioning of a part of the Application Software preventing it from operation. In case of such errors, the Provider undertakes to start remedying the situation within 4 business hours from demonstrable discovery of the error by the Provider or from the moment of demonstrable reporting of the error by the Client's authorized representative in writing through e-mail or helpdesk application. The Provider undertakes to remedy such error within 3 business days from starting to remedy the error. This provision shall apply, unless agreed otherwise in light of the nature of the error demonstrably, in writing, between the authorized representatives of the Client and the Provider.
- 2.03 A mid-level error (category B) shall mean an error in the form of non-functioning of a part of the Application Software outside category A, which however significantly limits functional use of the Application Software for the purpose it is designed to serve. In case of such errors, the Provider undertakes to start remedying the situation not later than on the next business day following after demonstrable discovery of the error by the Provider or from the moment of demonstrable reporting of the error by the Client's authorized representative in writing through e-mail or helpdesk application. The Provider undertakes to remedy such error within 5 business days from starting to remedy the error. This provision shall apply, unless agreed otherwise in light of the nature of the error demonstrably, in writing, between the authorized representatives of the Client and the Provider.
- 2.04 Low-level error (category C) shall mean an error in the form of limited functionality of the Application Software or the behavior of the Application Software outside categories A or B. In

case of such errors, the Provider undertakes to start remedying the situation within 2 business days from demonstrable discovery of the error by the Provider or from the moment of demonstrable reporting of the error by the Client's authorized representative in writing through e-mail or helpdesk application. The Provider undertakes to remedy such error within 10 business days from starting to remedy the error. This provision shall apply, unless agreed otherwise in light of the nature of the error demonstrably, in writing, between the authorized representatives of the Client and the Provider.

- 2.05 If an error is reported outside the helpdesk operating timeframe, the start of remedying an error deadline as well as the remedying deadline under paragraphs 2.02 to 2.04 hereof shall be calculated from the beginning of the next helpdesk operating period.
- 2.06 The Provider undertakes to endure monthly availability of the Application Software defined in Article 1.01 clause a) hereof in the minimal rate of 95 %. The availability of the Application Software shall be evaluated within the frame of each calendar month. The monthly system availability percentage shall be, for that purpose, calculated as follows:

$$A_m = (T_{ok} - T_{err}) / T_{ok} * 100$$

A_m shall mean monthly availability of the Application Software in %

T_{err} shall mean the total period of unavailability in the monitored period

T_{ok} shall mean total period of monitored availability or also the time of service operation.

A monitored period shall mean time from 08:00 AM to 05:00 PM on every business day of the given calendar month.

The Application Software shall be deemed unavailable in cases, where it shows error of A or B category.

A period of unavailability shall mean the time from demonstrated discovery of an error by the Provider or demonstrable reporting of an error by the Client's authorized representative by means specified in this Agreement (hereinafter the "Reporting") until the unavailability is remedied.

Unavailability period shall not include periods of unavailability of the Application Software caused by defects demonstrably outside the scope of this Agreement (e.g. defect of hardware, network infrastructure, operating system, restoration period etc.).

Unavailability period shall further not include periods of defects caused by force majeure, i.e. events occurring independently from the will of the Provider preventing the Provider from performing its obligations, provided that the Provider cannot be reasonably expected to overcome or avoid the consequences of such event or that the Provider could have been expected to reasonably foresee such obstacle at the moment of creation of such obligation. Unavailability period shall not include the time necessary to perform planned maintenance of the Provider. Also not included in unavailability periods shall be the time, during which the Provider's employees are prevented from accessing the system for repairs by the Client.

Article 3
Rights and Duties of the Provider

- 3.01 The Provider shall provide the Services under this Agreement at its own responsibility and shall provide all economic, material and personnel elements so that the purpose of this Agreement is fulfilled.
- 3.02 Throughout the time of rendition of the Services under this Agreement, the Provider shall render the Services in the highest quality and proceed with expert care, always mindful of the interest of the Client.
- 3.03 The Provider shall observe the Client's instructions. The Provider shall immediately inform the Client about all circumstances ascertained during the Provider's activity hereunder, which might influence rendition of the Services hereunder or the instructions given by the Client or their modification. The Provider shall always notify the Client of inappropriateness (if any) of the Client's instructions; if the Client insists on its instructions in spite of being warned by the Provider, the Provider shall be released from its liability for errors and defects (if any) demonstrably resulting from implementation of such inappropriate instructions.
- 3.04 The Provider undertakes to hand-over to the Client, without undue delay after entering into this Agreement, a list of persons, who shall participate in rendering the Services hereunder. The list shall be drafted for the purpose of granting access rights in the Client's building. In the list, people shall be identified by their names and surnames and also by their employer (or contractor, if such persons are not employees). The Provider shall provide such list of persons to the Client with an explicit consent of the listed persons to their personal data being processed by the Client for the purpose of ensuring their access in the Client's building and to the appropriate portions of the Client's information system. In case of breach of the mentioned duty, the Provider shall bear full responsibility under the Personal Data Protection Act. The Client undertakes to process the collected personal data solely for the purpose of rendition of the Services under Act no. 101/2000 Coll., on personal data protection and amendment of certain other acts, as amended (hereinafter also the "PDPA") until such consent is revoked in writing. Defining specific working hours and stay of persons rendering the Services hereunder in the premises of the Client's property shall be agreed in advance by the Provider with the Client, whereof a record shall be drafted and confirmed by authorized representatives of the Parties. The list of persons shall be immediately updated and handed-over to the Client by the Provider in case of any changes in the personnel.
- 3.05 The Provider undertakes to provide the Client, immediately after entering into this Agreement, a completed and signed application for access in the Client's information system (e.g. servers, infrastructure sections) for persons participating in the rendition of the Services hereunder. If, during the implementation of this Agreement, the Provider should require a change in the list of persons accessing the Client's information systems, the Provider shall, in each case, first apply for termination of access rights of the people, whose authorization is to be cancelled, and, at the same time, apply for access rights for people, who should obtain new right of access in the system. The Provider shall file such applications for granting/terminating the access rights in the Client's information system by using a form attached to this Agreement as its Appendix no. 2. The Client shall assess such application within two business days following the day of its delivery. When assessing any such application, the Client can require additional information regarding the purpose of the application. A copy of the approved or rejected application shall be handed-over by the Client to the Provider. In relation to the accesses into the Client's information systems, the Provider shall further adhere to the following duties:

- The Provider shall make sure and shall be responsible, throughout the period of rendering performance hereunder, for only people, in respect of whom an application for information system access rights was filed and, at the same time, in respect of whom such application was approved by the Licensee's IT Security Manager (hereinafter the "ISM"), actually accessing the appropriate sections of the Client's information system. At any time throughout the performance of this Agreement, the Client shall be authorized to check, which people actually access the appropriate part of the Client's information system and, in such case, the Provider shall always provide and prove such information to the Client. Any breach of this duty by the Provider shall be deemed material breach of contractual obligations by the provider.
 - The assigned access rights can only be used by the person, in respect of whom an application was approved by the ISM. Such person shall not be authorized to pass the assigned access rights to any third party. Any violation of the mentioned duty shall be considered material breach of contractual obligations by the Provider.
 - In case of termination of employment of an employee of the Provider having access rights, the Provider shall apply for termination of access rights of such employee to the Client's information system within two business days from the relevant event. The Provider shall take analogous course of action if the reason or need of the Provider's employee having access rights to the Client's information system ceases. Any violation of the mentioned duties shall be considered material breach of contractual obligations by the Provider.
- 3.06 The Provider shall take part in meetings called by the Client regarding the rendition of the Services under this Agreement. Unless specified otherwise, the authorized representative in technical matters shall always attend such meetings on behalf of the Provider.
- 3.07 The provider hereby undertakes to collaborate with any experts or other professionals designated by the Client during the performance under this Agreement in order to achieve the purpose of this Agreement.
- 3.08 The Provider hereby represents that the Provider holds, as of entering into this Agreement, an insurance policy covering third-party liability for damage caused by its business activity up to at least CZK 5,000,000 (in words: five million Czech crowns) with a deductible of not more than 10 % and undertakes to maintain the said policy throughout the duration of this Agreement and at least 6 months after terminating the activities under this Agreement. The Provider shall produce the policy or another certificate issued by the appropriate insurance company if so required by the Client.
- 3.09 The Provider undertakes to adopt all necessary measures to prevent any damage to the Client's property or health of the Client's employees when rendering Services under this Agreement.

Article 4 **Rights and Duties of the Client**

- 4.01 The Client shall timely provide the Provider with complete, true and well-organized information absolutely necessary to render the Services under this Agreement, unless the

nature of the information indicates that such information should be procured by the Provider itself as a part of the performance hereunder rendered.

- 4.02 The Client shall create suitable working conditions for rendition of the Services hereunder by the Provider and shall provide the Provider, throughout the duration of this Agreement, necessary assistance if the Provider reasonably asks for such assistance. This shall especially include handing-over documents and other information essential to the rendition of the Services and allowing access into the Client's premises. Any request for assistance originating from the Provider shall be in writing, addressed to the Client's representative in technical matters. Any request shall be presented in an advance sufficient, in light of the Client's business hours and the scope of assistance required (e.g. scope of the requested documents or activity), to be even able to reasonably expect the actual assistance within the given timeframe.
- 4.03 The Client shall be authorized to specify the time of rendition of Services in the Client's premises according to the Client's needs.
- 4.04 The Client shall be entitled to request the attendance of any of the Provider's representatives and the Provider shall secure the attendance of such representative at any meeting.

Article 5 Price of the Services

- 5.01 The Parties have agreed that the price of the Services under Article 1 and 2 hereof, if rendered duly and timely in accordance with terms and conditions herein specified, shall be:
 - (a) CZK 157,500 not including VAT, i.e. CZK 190,575 including VAT for every calendar quarter of rendition of Services under paragraph 1.01 clauses a) to c) of this Agreement, and
 - (b) CZK 2,500 not including VAT, i.e. CZK 3,025 including VAT for every man-hour of rendition of Services ordered according to paragraph 1.01 clause d) hereof.
- 5.02 The price specified in paragraph 5.01 hereof shall be the maximum and unsurpassable price including also all costs of the Provider related to rendition of the Services within the scope defined in Articles 1 and 2 hereof. The price specified in paragraph 5.01 clause a) is hereby agreed as fixed price.
- 5.03 If, during the validity of this Agreement (i.e. after this Agreement is entered into), the valid VAT rate is changed (i.e. increased or decreased), the Provider shall reflect such change in invoicing the price of the Services, i.e. increase or decrease the price by the change in VAT.

Article 6 Invoicing and Payment Terms

- 6.01 The Client shall pay the Provider the price specified in paragraph 5.01 clause a) hereof based upon invoices issued by the Provider. The Services under paragraph 1.01 clauses a) to d) hereof shall be invoiced quarterly, always by the 15th day of the month following the calendar quarter, in respect of which the rendition of the Services is invoiced.
- 6.02 The Client shall pay the Provider the price specified in paragraph 5.01 clause b) hereof based upon an invoice issued by the Provider after rendering Services based upon a specific order by the Client. The invoice shall be issued always after finishing and handing-over the product

of each order by means of an acceptance certificate under paragraph 1.01 clause d). Attached to the invoice shall be a copy of mutually signed acceptance certificate under paragraph 1.01 clause d) certifying the acceptance of the product of the given order without reservations.

- 6.03 The invoices shall meet all formal requirements prescribed for a tax and accounting invoice as specified by Act no. 235/2004 Coll., on VAT, as well as Act no. 563/1991 Coll., on bookkeeping, as amended. If a presented invoice fails to meet the formal requirements prescribed by law or by this Agreement, the Client shall be entitled to return such invoice by its maturity date to the Provider, stating the grounds for returning the invoice. In such case, a new maturity period starts on the day of delivering the corrected invoice to the Client.
- 6.04 The invoices shall be due in 30 days. The mentioned period shall be calculated from the day of demonstrable delivery of the invoice free from any errors to the Client. The Parties have agreed that the duty to pay the invoice shall be met on the day when the corresponding amount is deducted from the Client's account in favor of the Provider.
- 6.05 The Client hereby reserves the right to limit the scope of this Agreement or the right to not implement the entire performance hereunder. The Client shall be entitled to exercise the mentioned right by written notification addressed to the Provider.
- 6.06 If the Client delays payment of any sums under this Agreement, the Client shall pay the Provider a late interest payment on the outstanding sum in the amount stipulated by applicable law.
- 6.07 The Provider acknowledges its own financial costs related to rendition of performance under this Agreement and shall not demand any financial performance throughout the period of rendition of Services exceeding the agreed price payment conditions as specified in Article 6 hereof.

Article 7 Place of Performance

- 7.01 The Parties have agreed that the Services and activities under this Agreement shall be provided at the Client's office located in Prague, Šrobárova 48, 100 41 Prague 10 and at the Provider's registered seat.
- 7.02 Services and activities under this Agreement can be provided remotely using networks and means of electronic communication (under Act no. 127/2005 Coll., on electronic communications), as long as allowed by the nature of the performance rendered.

Article 8 Provider's Subcontracts

- 8.01 The Provider shall render all performance under this Agreement exclusively through its own employees.

Article 9 Confidential Information Protection

- 9.01 The Provider shall keep confidential all information obtained during the performance under this Agreement, unless such information is designated for publication by law or unless such

information is publicly known. The Provider also undertakes not to allow any person to disclose the confidential information to unauthorized third parties, unless stipulated otherwise in this Agreement. The Provider shall treat as confidential information provided by the Client to the Provider or obtained by the Provider in connection with performing its obligations hereunder.

- 9.02 For the purpose of this Agreement, following information shall not be considered confidential:
- (a) information, which becomes publically accessible to the public other than by its disclosure by the Provider;
 - (b) information obtained by the Provider from a source other than the Client, as long as such information is designated as public by the disclosing entity.
- 9.03 The Provider undertakes to use the confidential information exclusively to perform its duties under this Agreement. The Provider further undertakes that neither the Provider nor another person or entity, to which confidential information is disclosed by the Provider in accordance with this Agreement, shall disclose such information to any third party, with the exception of following cases:
- (c) confidential information disclosed to people or entities, to whom such information must be disclosed in order to perform obligations of the Provider deriving out of this Agreement;
 - (d) confidential information disclosed with the previous written approval of the Client;
 - (e) confidential information disclosed under applicable law or where such duty derives from a final and lawful decision of a competent authority issued based upon its statutory jurisdiction. Such circumstance shall be immediately demonstrated by the Provider to the Client if so requested.
- 9.04 The Provider further undertakes to secure protection of confidential information against unauthorized access by third parties. If the Provider reasonably suspects that confidential material was accessed (obtained) without proper authorization, the Provider shall notify the Client immediately.
- 9.05 The Provider shall hand-over to the Client without unnecessary delay all materials and things received from the Client or on the Client's behalf during rendering performance hereunder, without unnecessary delay after expiration of this Agreement. The Provider shall delete any confidential information stored in electronic format not later than on expiration of the statutory archiving period if the Provider is under statutory archiving obligation.
- 9.06 The duty of confidentiality remains in effect even after termination of this Agreement.
- 9.07 The Provider undertakes to bind by the specified duty of confidentiality all its employees without undue delay.
- 9.08 Throughout the duration of this Agreement and even after, the Client shall be authorized to publish this Agreement or any portions hereof regarding performance hereunder rendered, which the Provider acknowledges and to which the Provider consents.

Article 10

Contractual Penalties

- 10.01 If the Provider breaches the duty specified in Article 8 hereof, the Provider shall pay the Client for each such breach a contractual penalty of CZK 100,000.
- 10.02 If the Provider breaches any of its duties regarding the duty of information protection and confidentiality, the Provider shall pay the Client a contractual penalty of CZK 100,000 for every single breach.
- 10.03 In case of the Provider delaying the start of remedying a critical error or a critical error specified in paragraph 2.02 hereof, the Provider shall pay the Client a contractual penalty of CZK 5,000 for every started hour (regarding the start of work) or every started business day (regarding the remedying) of delay behind the deadlines defined in paragraph 2.02 hereof.
- 10.04 In case of the Provider delaying the start of remedying a mid-level error or a mid-level error specified in paragraph 2.03 hereof, the Provider shall pay the Client a contractual penalty of CZK 3,000 for every started business day of delay behind the deadlines defined in paragraph 2.03 hereof.
- 10.05 In case of the Provider delaying the start of remedying a low-level error or a low-level error specified in paragraph 2.04 hereof, the Provider shall pay the Client a contractual penalty of CZK 1,000 for every started business day of delay behind the deadlines defined in paragraph 2.04 hereof.
- 10.06 In case of delay on the part of the Provider of rendition of Services under paragraph 1.01 clause d) hereof behind the deadline stated in the Client's order, the Provider shall pay the Client a contractual penalty of CZK 5,000 for every started day of delay.
- 10.07 If the Provider breaches any of its duties imposed in this Agreement or related to performance under this Agreement, the Provider shall pay the Client a contractual penalty of CZK 5,000 for each day of delay, as long as such breach of duty lasts, unless specified otherwise herein.
- 10.08 If, during the existence of the contractual relation, the Provider stops rendering performance hereunder, the Provider shall pay the Client a contractual penalty corresponding to the pro rata portion of the price for rendition of the Services under Article 5 hereof for each day of delay of rendering performance. Such delay shall constitute a material breach of the Provider's obligation.
- 10.09 By paying the contractual penalty, the Provider shall not be released from the duty to provide the Client the performance hereunder agreed or from the duty to pay any damages, even in excess of the contractual penalty.

Article 11

Term

- 11.01 This Agreement is entered into for a definite period of time, namely 4 years from the day of effect of this Agreement.

- 11.02 The Parties have agreed on the option of terminating this Agreement before the expiration of the period specified in the preceding paragraph based upon the following grounds:
- a) Termination or rescission of the Agreement.
 - b) Loss of the Provider's business license necessary to render the Services hereunder.
 - c) Written agreement of the Parties.
- 11.03 In case of termination of this Agreement, all provisions agreed between the Parties regarding the Provider's liability for damage, contractual penalties and confidentiality shall survive the expiration of this Agreement.

Article 12

Termination and Rescission of the Agreement

- 12.01 Either Party shall be authorized to terminate this Agreement. The Client shall be entitled to terminate this Agreement without stating any grounds, provided that in such case the Client shall give a 6 months' notice with the notice period starting on the day immediately following the day of demonstrable delivery of the termination notice to the other Party. The Provider shall be authorized to terminate the Agreement only in case of the Client delaying payment of an invoice for the Services; such delay of the Client shall be required to be more than 60 days. The notice period for the Provider shall be 6 months starting on the day immediately following the day of demonstrable delivery of the termination notice to the other Party.
- 12.02 After receiving the termination notice specified in the preceding paragraph, the Provider shall carry on with the activity herein specified until the end of the notice period, unless instructed otherwise by the Client. At the same time, the Provider shall inform the Client about any measures necessary to prevent imminent damage to the Client resulting from any unfinished activity.
- 12.03 A termination of this Agreement shall not cancel a Party's entitlement to contractual penalty or payment of damages. If this Agreement is terminated by notice, the Provider shall be entitled to demand payment for actual and demonstrable costs related to the Services implemented thus far, unless agreed otherwise. The Client shall be authorized to receive, and the Provider shall – in such case – hand-over to the Client the work done thus far as well as unfinished work and services within 15 days from the day of expiration of the Agreement. The Parties shall draft a hand-over record regarding such handing-over and acceptance. As of the day of the mentioned record, the Provider shall hand-over to the Client documents and information regarding the unfinished services.
- 12.04 Any termination notice shall be in writing and demonstrably delivered to the other Party. A termination notice shall be deemed duly delivered also when delivered using data box. If data-box delivery is impossible due to objective reasons, demonstrable delivery through post or messenger service shall be deemed due delivery.
- 12.05 The Parties have agreed that this Agreement can only be rescinded in cases explicitly stated in this Agreement and also in case of material breach of contractual obligations by the other Party. A breach of duty shall be deemed material breach of contractual duty in cases stipulated by applicable law or by this Agreement. Any failure to perform a contractual duty in a reasonable additional time period provided in a written request shall also constitute a material breach of contractual duty, as well as bankruptcy proceedings against a Party or rejection of insolvency petition due to lack of assets of a Party.

- 12.06 The Client's delay of payment of a price rightfully invoiced by the Provider for the Services under paragraph 5.01 by more than 60 days shall constitute a material breach of contractual duty by the Client, authorizing the Provider to rescind this Agreement.
- 12.07 The Provider's breach of any duty related to the duty of confidentiality as herein specified or the Provider's breach of the duty specified in Article 8 hereof shall constitute material breach of contractual obligation authorizing the Client to rescind this Agreement.
- 12.08 If either of the Parties rescinds this Agreement, the rescinding Party shall notify the other Party thereof in writing. The rescission notice shall specify the circumstances, respectively grounds of rescission and a direct quote of a law or a provision of this Agreement authorizing the rescinding Party to rescind the Agreement. Without the mentioned formalities, no rescission shall be valid, except for cases, where the right of rescission derives directly from a statute. A rescission notice can also include a declaration that the rescinding Party rescinds this Agreement if the corresponding breach of duty is not rectified within a period specified in the notice, as long as providing such period is possible in light of the duty breached.
- 12.09 In case of rescission of this Agreement, any rescission shall be effective on delivery of written notice regarding the rescission to the other Party, unless the rescission states a later moment of the effect of the rescission. A rescission notice shall be deemed duly delivered if delivered by post, messenger service or the other Party's data box.
- 12.10 The Client shall also be authorized to rescind the Agreement without bringing any financial claims from the part of the Provider if it is clear that the agreed Services or activities will not be provided duly or on time as specified in this Agreement or on the basis of this Agreement.

Article 13

Force Majeure

- 13.01 The Parties shall not be responsible for partial or complete non-performance of their contractual obligations resulting from force majeure. Force majeure shall include circumstances arising after the signature of this Agreement resulting from unavoidable events of extraordinary nature, directly affecting rendition of performance herein agreed, unforeseeable by the Party, who invokes the existence (influence) of force majeure, before entering into this Agreement, and which such Party cannot influence in spite of exerting every possible effort.
- 13.02 In case of force majeure occurrence all deadlines for performance of contractual obligations shall be extended by the period of duration of the effect of force majeure.
- 13.03 A Party afflicted by force majeure must notify the other Party in writing about the beginning and end of force majeure event immediately, in any case not later than within fifteen (15) days. A Party, who fails to do so, cannot successfully invoke force majeure clause.

Article 14

Severability

If any of the provisions of this Agreement is or becomes invalid, ineffective or unenforceable, the remaining provisions of this Agreement shall remain valid and effective. Instead of such invalid, ineffective or unenforceable provision, provisions of generally binding laws and regulations governing the issue of mutual rights and obligations of the Parties shall apply. In such case, the Parties shall regulate their relation by agreeing on a different contractual

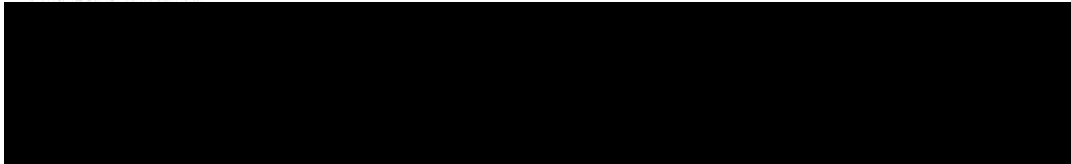
provision best suitable as to its result to the intention originally expressed by the invalid or ineffective or unenforceable provision. If this Agreement is found to lack any provision, which otherwise would be reasonable in the sake of completeness of regulation of mutual rights and duties, the Parties shall exert maximum effort to supplement such provision in this Agreement.

Article 15

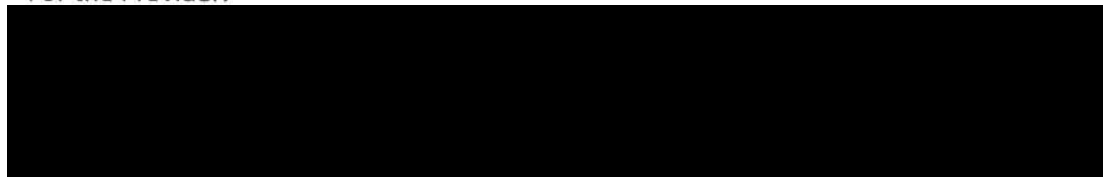
Final Provisions

15.01 Following persons shall be authorized to act on behalf of the Parties:

For the Client:



For the Provider:



15.02 Inseparable part of this Agreement shall be:

- | | |
|----------------|--|
| Appendix no. 1 | Application Software manufacturer's licensing terms and conditions regarding maintenance |
| Appendix no. 2 | Application form regarding access to the Client's information systems (e.g. servers) |

15.03 This Agreement can only be changed by written, numbered agreement confirmed by both Parties, explicitly designated as amendment of the Agreement. No other records, protocols etc. shall be deemed to modify this Agreement.

15.04 In case of circumstances preventing either Party from rendering performance hereunder, such Party shall immediately notify the other Party.

15.05 This Agreement is drafted in 2 counterparts, 1 to be kept by each of the Parties.

15.06 The Parties declare that they have read this Agreement carefully and that the content of this Agreement is clear and comprehensible to them. The Parties further declare that this Agreement is not being entered into in distress or under otherwise unilaterally disadvantageous conditions.

15.07 All issues not specifically agreed upon in this Agreement shall be governed by the applicable provisions of the Civil Code and other valid laws of the Czech Republic.

15.08 This Agreement becomes valid on the day of being signed by both Parties hereto and effective on signature of acceptance certificate for the 3rd stage of implementation according to the License Agreement for the Application Software resulting from public procurement VZ52/2015 "Implementation of eCTD tool in SIDC", whereby the result of the 3rd stage of

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implementation shall be accepted without reservations by the Client in accordance with paragraph 2.5 clause c) of the License Agreement.

In testimony of this entire Agreement being a product of their genuine, solemn and free will, the representatives authorized to enter into this Agreement on behalf of the Parties, affix their signatures below.

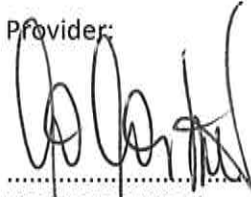
In Prague on 29th April 2016

In Frankfurt on 27th April 2016

Client:

Státní ústav pro kontrolu léčiv
Šrobárova 48
100 41 Praha 10
(100)

Provider:


.....
Wolfgang Witzel
President

.....
PharmDr. Zdeněk Blahuta
director

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LORENZ LIFE SCIENCES GROUP
LORENZ Release and Support Services - service through Annual Software Maintenance

LORENZ shall provide Release and Support Services (RSS) (as defined herein) (formerly Technical Support Services – TSS) 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 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").

I. DEFINITIONS

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

EFFECTIVE DATE means the date from which RSS 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.

ERROR means a defect, fault, loss or degradation of service and/or functionality in the SOFTWARE which is escalated to LORENZ, in each case, in accordance with the Support Process.

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

RELEASE SERVICES means the provision of MAJOR RELEASES, STANDARD RELEASES and SPECIFIC RELEASES (each defined below), if any, to the SOFTWARE, as well as corresponding documentation, to Customer.

- **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 5.0 to Software 5.1). MAJOR RELEASES are usually released in April and October each year and are communicated via LORENZ ID.
- **STANDARD 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 5.0 to Software 5.0.1). STANDARD RELEASES are communicated via LORENZ ID.

- **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 5.0.0 to Software 5.0.0.01). SPECIFIC RELEASES are normally not communicated via LORENZ ID.

SERVICE PERIOD means the period for which RSS have been agreed between LORENZ and Customer beginning at the EFFECTIVE DATE. Except as otherwise stated by LORENZ, RSS are provided in SERVICE PERIODS consisting of twelve (12) months.

SERVICES FEES means the fees for RSS specified in a LORENZ invoice corresponding directly to the RSS.

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

- **SEVERITY 1** means an ERROR 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** means an ERROR 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 ERRORS could include one or more



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of the following characteristics: (i) severe but intermittent ERRORS; (ii) loss of secondary or administrative functionality; or (iii) continual or repeated problems.

- **SEVERITY 3** means an ERROR 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 ERRORS 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** means an ERROR 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 ERRORS 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 means SOFTWARE offered on the LORENZ price list, and all the components shipped with the SOFTWARE.

SUPPORT SERVICES 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 or upgrade of a LORENZ product, regardless of the number of communications required.
- A **FUNCTIONAL SUPPORT** service request is defined as assistance with one question relating to the product functionalities of a LORENZ product, regardless of the number of communications required.
- A **VALIDATION SUPPORT** service request is defined as assistance with one question relating to a validation report created by LORENZ eValidator, regardless of the number of communications required.

SUPPORT SERVICES do not cover the following:

- Service requests for implementation and configuration assistance.
- 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 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.

II. SERVICE TERMS

II.1. Provision of Services

Subject to the terms of this Agreement, LORENZ shall, during the SERVICE PERIOD, provide Customer with RSS.

II.2. Service/Support Hours

LORENZ provides RSS during its regular business hours as stated on <http://www.lorenz.cc/businesshours>.

II.3. Purchase Requirements

Except as otherwise provided for by LORENZ, Customer may purchase initial RSS 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'S discretion and will automatically update to LORENZ'S then-current Service Terms upon any renewal of RSS.

II.4. Exclusions

Services specifically excluded in the definition of SUPPORT SERVICES, general advisory services as well as correction of ERRORS 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 and shall be billed to Customer on a time and materials basis.

III. SERVICES FEE TERMS

III.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.



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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 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.

III.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.

III.3. Incidental Expenses

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

IV. MISCELLANEOUS TERMS

IV.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'S 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'S PRICING REFLECTS THIS ALLOCATION OF RISK AND THE LIMITATION OF LIABILITY SPECIFIED HEREIN.

IV.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 IV.2. shall be considered enforceable.

IV.3. Termination

Customer may terminate LORENZ'S RSS at any time by notifying LORENZ in writing at least thirty (30) days before the end of the pertinent SERVICE PERIOD. LORENZ'S RSS shall be terminated thirty (30) days after receipt of such notice.

LORENZ may suspend or terminate Customer's RSS 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.

IV.4. Response Times

Response times for critical error (A category) and medium-level error (B category) are only valid if all of following conditions apply:

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

..... Id. no.: (hereinafter the "Applicant") applies for assignment of access to SIDC servers

For its following employees:

.....

We ask for access rights to servers:

Server name	IP address

for the purpose of "Performance under agreement no. (order dated) and related orders"

Access to the servers can only be used for the specified purpose. The Applicant and the employees shall be obliged to protect the access rights against unauthorized use or any abuse. At the same time, they undertake to use the obtained information solely for the purpose, for which the access is granted, and not to disclose the information further.

The Applicant shall only disclose the access rights to its above-named employees charged with carrying out activities under the above-specified agreement / order. The Applicant undertakes to only access servers specified in the application and to notify the SIDC as soon as the need of accessing the servers ceases. The Applicant shall immediately notify SIDC about any employee, who was granted access right, who ceases to perform for the Applicant the activity, in respect of which the employee was granted access rights. Any transfer of access rights to another employee shall be subject to previous approval by SIDC to be granted based upon a newly filed application.

Unauthorized use of access rights by the Applicant or any of its employees shall be considered violation of the granted permit resulting in full liability for such violation under valid law.

The Applicant and its employees accessing SIDC servers undertake to fulfill all duties prescribed by Act no. 101/2000 Coll., on personal data protection, as amended, Act no. 148/1998 Coll., on the protection of secret information, as amended, as well as other valid law. By signing this application, the Applicant represents that its employees are fully informed about the duties stipulated by law mentioned in the preceding sentence.

The Applicant shall be liable to SIDC for any damage caused by breach of a duty herein specified or specified by valid law by the Applicant or its employee. The Applicant shall compensate SIDC for any such damage in full.

Date:

.....

Signature

Approved by the information security manager of SIDC

Date:

.....

Signature