

(Translation from Czech)

## **AMENDMENT No. 2 TO THE LICENSE 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  
(hereinafter the “**Licensee**”)

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 “**Licensor**”)

(this amendment, hereinafter the “Amendment”, the Licensor and the Licensee jointly hereinafter as the “Parties”)

### **Article 1 Opening Provisions**

1.1 On the April 29, 2016 the Parties concluded License Agreement (hereinafter as the “Agreement”) under which the Licensor grants the Licensee an authorization to use the below-specified Application Software designed to process registration documents in the eCTD/NeeS format:

*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*

*15x docuBridge user licenses (named)*

- *10x key for users*
- *5x for admin users*

*1x LORENZ eValidator OEM version*

- 1.2 Some modifications of Licensee's SW tool for recording electronic documents (AthenA) are necessary for efficient implementation and fulfilment of all activities in the second stage. Required modifications had to be postponed on the grounds of new legislative changes and their integration in the process (eIDAS). Therefore it is necessary to adjust the deadline for delivery of the second stage.
- 1.3 The Agreement shall change as stated below in the Article 2 of this Amendment.

## **Article 2**

### **The change of the Agreement**

- 2.1 The section 3., point 2. of the Appendix No. 2 to the Agreement shall be replaced by following provision:

*"Implementation of the Application Software in the Licensee's testing environment shall be carried out as part of the second stage. The second stage shall be handed-over by the Licensor to the Licensee for approval within ~~3 weeks~~ 90 days from acceptance of the previous stage and shall include the below-listed activities.*

- *Implementation and integration of the entire comprehensive proposal of solution of the Application Software in the Licensee's testing environment*
- *Implementation of communication among the concerned application within SIDC's testing environment*
- *Testing the Application Software in the testing environment (function, integration, performance). The Licensor shall design individual test scenarios to be used for the testing, which shall be presented to the Licensee for approval*
- *Implementation of role administration in the application through IIM in the testing environment*
- *Supplying user and technical documents for the installed Application Software*
- *Training of users and administrators, schedule to be determined by the Licensee"*

## **Article 3**

### **Final Provisions**

- 3.1 Except as set forth in this Amendment, the Agreement is unaffected and shall continue in full force and effect in accordance with its terms.
- 3.2 This Amendment is drafted in 2 counterparts, 1 to be kept by each of the Parties.
- 3.3 The Parties declare that they have read this Amendment carefully and that the content of this Amendment is clear and comprehensible to them. The Parties further declare that this Amendment is not being entered into in distress or under otherwise unilaterally disadvantageous conditions.
- 3.4 This Amendment becomes valid and effective on the day of being signed by both Parties hereto.

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

In Prague on .....

In Frankfurt on .....

Licensee:

Licensor:

.....  
PharmDr. Zdeněk Blahuta  
Director

.....  
Wolfgang Witzel  
President