

(Translation from Czech)

AMENDMENT No. 1 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*
- *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

- 1.2 Whereas within the translation of the Agreement from Czech to English were by mistake caused two discrepancies between Czech and English version of the Agreement, the Parties decided to eliminate such discrepancies by concluding this Amendment.
- 1.3 The Agreement shall change as stated bellow in the Article 2 of this Amendment.

Article 2 The change of the Agreement

- 2.1 The paragraph 3.1 of the Agreement shall be replaced by following provision:

"The Parties have explicitly agreed, as per Section 2366 subsection 1 clause a) of the Civil Code that the royalties for granting the License and rendition of services specified in Article 2 hereof shall be:

the price without VAT of CZK 2,480,000 (in words: two million and four hundred and eighty thousand Czech crowns).

VAT of CZK 520,800 (in words: five hundred and twenty thousand and eight hundred Czech crowns) corresponding to the VAT rate of 21 %.

Total price of CZK 3,000,800 including VAT (in words: three million and eight hundred ~~thousand~~ Czech crowns)."

- 2.2 The section 3., point 1. of the Appendix No. 2 to the Agreement shall be replaced by following provision:

"In the first stage, the Licensor shall carry out a thorough analysis of requirements of SIDC employees. As a part of this stage, the Licensor shall secure complete documents necessary to implement the Application Software in the SIDC's environment. Resulting from this stage shall be an approved document summarizing SIDC's requirements including a proposal of implementation of the Application Software in the Licensee's environment. This stage shall be handed-over for the Licensee's acceptance within 3 ~~weeks~~ ~~months~~ from signing the agreement. In this stage, following documents shall be presented to the Licensee for approval:

- *Schedule of fulfillment and implementation of the entire order approved by the Licensee.*
- *Analysis of SIDC's requirements including detailed specification of the Application Software, its functionality, technical solution and integration of the individual parts into the ITC infrastructure of the Licensee. The analysis shall be approved 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 13.6.2016

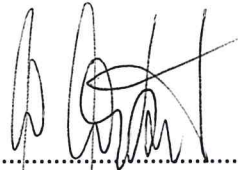
In Frankfurt on May 11th 2016

Licensee:


PharmDr. Zdeněk Blahuta
Director

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

Licensor:


Wolfgang Witzel
President

Lorenz
ARCHIV SYSTEME
GmbH
Eschborner Landstraße 75
60489 Frankfurt/M.
Telefon 069 / 7 89 91-901

