SERSTECH

Compliance Statement 21 CFR Part 11

To our valued customers:

This is a statement to certify that our *Serstech 100 Indicator Pharma version* and the software *ChemDash Pharma* to the best of our knowledge and understanding comply with the FDA 21 CFR Part 11 requirements for a closed system. We have made every effort to meet the necessary regulatory requirements in this regard.

It must be understood, however, that certain activities, such as implementation of security policies and requisite SOPs are the responsibility of the customer.

Furthermore, regulations and enforcement activities change over time.

Nevertheless, we ensure that with the above-mentioned qualifications, our customers will be in compliance when using our *Serstech 100 Indicator Pharma version* firmware in conjunction with the *ChemDash Pharma* software.

ChemDash Pharma is a proprietary software package that is utilized together with a Serstech 100 Indicator with Pharma version firmware installed.

Scope

Both our *Serstech 100 Indicator Pharma version* firmware and software *ChemDash Pharma* meet the 21 CFR Part 11 requirements, as defined in Subpart A, in Subpart B, and Subpart C for closed systems.

21 CFR Part 11 is the FDA rule that relates to the use of electronic records and electronic signatures. In response to industry requests, and in recognition of the increasing impact of electronic media on critical data in the regulated environment, the FDA met with members of the pharmaceutical industry in the early 1990s. The pharmaceutical industry was interested in how they could accommodate paperless record systems under GMP guidelines, and the FDA was additionally interested in developing a uniform approach, and ensuring the trustworthiness, reliability and integrity of the electronic records. The result was a final rule that became effective on August 20, 1997.

Key definitions follow:

Electronic record

"any combination of text, graphics, data, audio, pictorial, or other information representation in digital form that is created, modified, maintained, archived, retrieved, or distributed by a computer system"

Electronic signature

"a computer data compilation of any symbol or series of symbols executed, adopted, or authorized by an individual to be the legally binding equivalent of the individual's handwritten signature."

Closed system

"an environment in which system access is controlled by persons who are responsible for the content of electronic records that are on the system."

Digital signature

"an electronic signature based upon cryptographic methods of originator authentication, computed by using a set of rules and a set of parameters such that the identity of the signer and the integrity of the data can be verified."

Third-party software

Customers may choose to use third-party software packages, such as Data Management Systems or LIM Systems, in connection with ChemDash software results. Serstech AB takes no responsibility for the performance or compliance of such products, or for any difficulties arising from data or text transfer to such products.

Statement of 21 CFR Part 11 compliance

We recommend that each user retain a copy of this letter in validation files as part of regulatory documentation. Serstech AB has made every effort to understand and interpret the meaning and intent of the 21 CFR Part 11 regulations. We have drawn upon the advice and expertise of multiple sources, private industry experts and governmental. We believe that with proper due diligence on the part of the users of both *Serstech 100 Indicator Pharma* version and *ChemDash Pharma* the customer will be in full compliance.

Lund, Sweden, August 30, 2019

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Stefan Sandor, CEO

Serstech AB

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