



# SIMPATI e-Sign

The consistent solution ...

from electronic documentation of measurement values  
through to the delivery of electronic documents to the authorities



**Weiss Umwelttechnik GmbH**  
Simulationsanlagen • Messtechnik



# SIMPATI e-Sign captures biometric data based on your handwriting

## The consistent solution from electronic documentation of measurement values through to the delivery of electronic documents to the authorities

Many lawyers would like to see the introduction of a truly **active biometric component** to identify people. In their opinion, a handwritten electronic signature is the only real active declaration of in-

tent that could never be given unwillingly or by force.

**SIMPATI e-Sign** as a supplement to the software package compliant with FDA 21 CFR Part 11

**SIMPATI-Pharma** enables signing

all measurement data whilst capturing biometric data based on your handwriting.

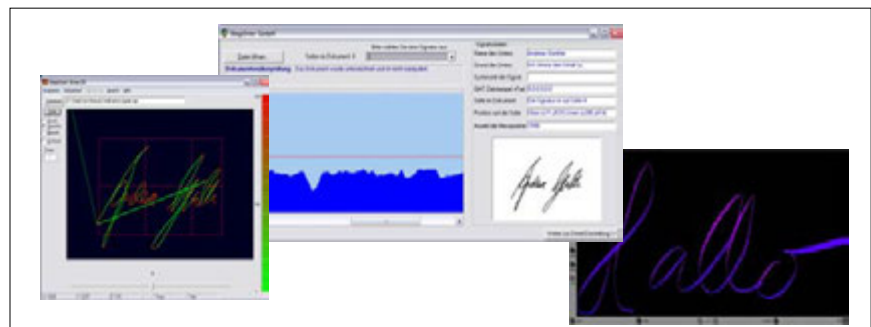
## SIMPATI e-Sign offers legal security, whereby the undersigned is clearly identifiable!

In order to also be able to identify the undersigned at a later date, there are special software graphic components which, in case of dispute, could be used by handwriting experts. An expert report stated that the judicial value as evidence is provided by a signature given using this technology.

It is confirmed by an independent handwriting expert, allowed to appear in court, that the same conclusions can be reached from

these components as from a handwritten signature on paper. Functional security was verified

based on more than 200,000 signatures.



## All Aspects from FDA 21 CFR Part 11 are complied with. The system can be easily qualified.

This system is based on a state-of-the-art electronic signature which is accepted for all documents which do not explicitly require the written form by law (such as the German Civil Code), directives or standards.

For all legally valid internal company signatures, i.e. including those in the laboratory, this way of signing is sufficient and also compliant with FDA 21 CFR Part 11.

The data are encoded using a multi-stage, asymmetrical encoding process. This code is filed in the document. A hash value (checksum) is formed over the signed document and stored. Even the transmission from the high-resolution graphic tablet to the PC is encoded. A so-called public key/private key infrastructure (PKI) is used when sealing the document. These codes, however, must be generated



from an independent office and, for legal security purposes, the private key must be stored in the same place. The storage of the data is carried out in accordance with ISO 19005 in a generally readable data format, with no possibility of changes being made to it, suitable for long-term storage.



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