SwanGuard

Operator's Manual

SWISS ✚ MADE

SwanGuard

Customer Support

Swan and its representatives maintain a fully trained staff of technical specialists around the world. For any technical question, contact your nearest Swan representative, or the manufacturer:

Swan Analytische Instrumente AG
Studbachstrasse 13
8340 Hinwil
Switzerland

Internet: www.swan.ch
E-mail: support@swan.ch

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1. About SwanGuard

Introduction   SwanGuard is a program that creates signed PDFs from encrypted records of Swan instruments (file extension *.sef).
The encryption used in the SEF file format ensures that the records originate from a Swan instrument and have not been manipulated.
The generated PDF reports are digitally signed and meet the requirements of the relevant standards in the pharmaceutical industry, e.g. 21CFR Part 11.

2.   Validating the SwanGuard Certificate

Note: These instructions assume that Adobe Acrobat Reader is used to display PDFs. If you are using a different program, follow the software manufacturer's instructions for validating a certificate.

1   Start the SwanGuard program.

2   Select **File** > **Export digital signature**.

3   Save the certificate in a folder of your choice.

4   In the next window, confirm with "Yes"
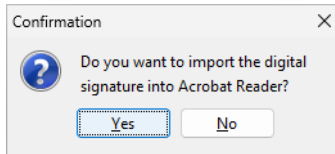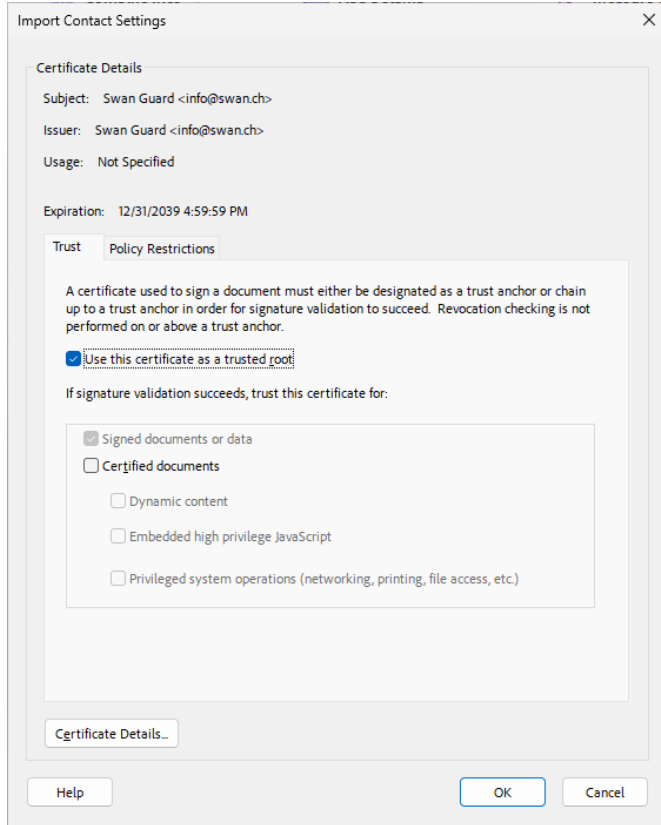

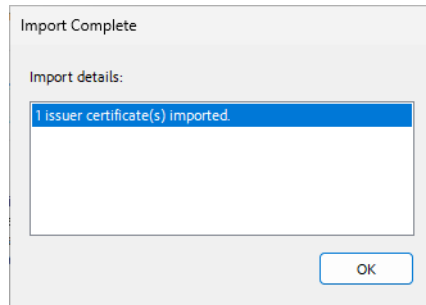$\Rightarrow$ *Adobe Acrobat Reader is started automatically*

5   In the "Data Exchange File - Import Contact" window, click on the "Set contact trust" button.
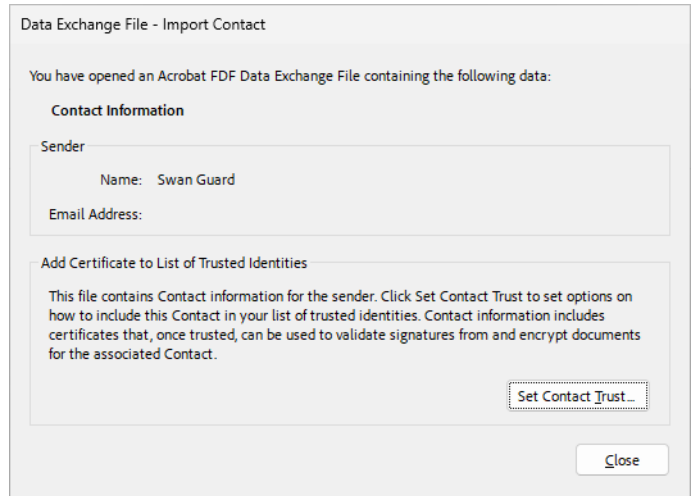
6 In the next window, check the box next to "Use this certificate as trusted root" and confirm with "OK".

Import Contact Settings ✕

Certificate Details

Subject: Swan Guard <info@swan.ch>

Issuer: Swan Guard <info@swan.ch>

Usage: Not Specified

Expiration: 12/31/2039 4:59:59 PM

Trust   Policy Restrictions

A certificate used to sign a document must either be designated as a trust anchor or chain up to a trust anchor in order for signature validation to succeed. Revocation checking is not performed on or above a trust anchor.

☑ Use this certificate as a trusted root

If signature validation succeeds, trust this certificate for:

☑ Signed documents or data
☐ Certified documents
   ☐ Dynamic content
   ☐ Embedded high privilege JavaScript
   ☐ Privileged system operations (networking, printing, file access, etc.)

Certificate Details...

Help   OK   Cancel

⇒ *A confirmation appears that the certificate has been imported.*

Import Complete

Import details:

1 issuer certificate(s) imported.

OK

7 Close the "Data Exchange File - Import Contact" window.

8 If you want to view PDF reports on other PCs, proceed as follows:
– Copy the SwanGuard.fdf file (see step 3) to these PCs and double-click on it to start the validation.
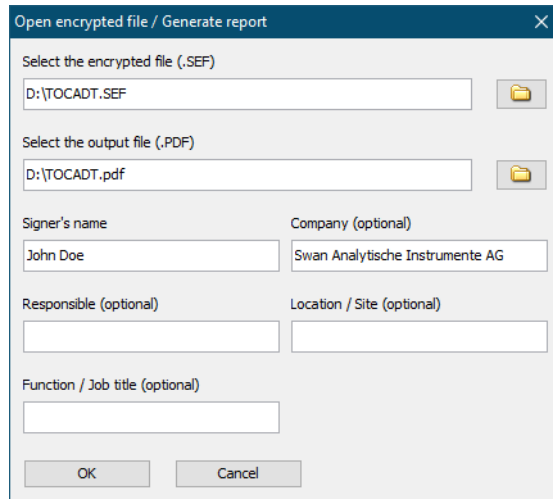– Proceed as described in steps 5 to 7.

3. Generating a PDF Report

Writing Audit Trail records to SD card

1 Proceed as described in the Operator's Manual of the AMI-II instrument to write the logger files to the SD card.

2 Remove the SD card from the AMI-II transmitter.

3 Copy all logger files to the computer and delete them from the SD card.

4 Insert the SD card back into the SD card slot of the AMI-II transmitter.

Generating a PDF report

1 In SwanGuard, select **File** > **Open Swan Encrypted File**.

2 Make the following settings in the window that opens:
 – Select the *.sef file and the target folder for the PDF report file by clicking on the 📁 buttons next to the input fields.
 – Enter the signer's name in the corresponding field.
 – If necessary, fill in the "Company", "Responsible", "Location" and "Function / Job title" fields.

Open encrypted file / Generate report   ✕

Select the encrypted file (.SEF)

| D:\TOCADT.SEF | 📁 |

Select the output file (.PDF)

| D:\TOCADT.pdf | 📁 |

| Signer's name | Company (optional) |
| John Doe | Swan Analytische Instrumente AG |

| Responsible (optional) | Location / Site (optional) |
| | |

Function / Job title (optional)

| |

| OK | Cancel |

3 Confirm with "OK".
 ⇒ *SwanGuard generates the PDF report.*

4.   Checking the Certificate Status

Open the PDF report in Adobe Acrobat Reader. The certificate status is automatically checked and displayed after a few seconds.

A green circle with a check mark indicates that the PDF file has not been modified since it was created and signed by SwanGuard.

Signed and all signatures are valid.

An orange triangle indicates that the SwanGuard certificate has not been validated yet. Proceed as described on p. 3 to validate the certificate.

At least one signature has problems.

A red circle indicates that the signature is invalid. This means that the PDF file has been modified since it was signed.

At least one signature is invalid.

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Swan Analytical Instruments · CH-8340 Hinwil
www.swan.ch · swan@swan.ch

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