



Digital IDs for FDA Electronic Submissions Gateway (ESG)

Due to recent FDA regulation changes, Digital IDs a.k.a. Digital Certificates are required for submitting electronic documentation to the FDA. GlobalSign is an approved provider of digital IDs for the FDA Electronic Submissions Gateway (ESG).

http://www.accessdata.fda.gov/esg/userguide/webhelp/Digital_Certificates.htm .

GlobalSign's **PersonalSign 2 Pro** is the compatible Digital ID to be used when submitting documents with the ESG. You can order a PersonalSign 2 Pro at :

<http://www.globalsign.com/authentication-secure-email/digital-id/buy-personalsign-2-pro.html>

Important Information and Ordering Instructions

1. The “**FDA recommends using certificates with 3 years validity**”.
2. PersonalSign2 Pro digital IDs are Class 2 digital certificates that provide a vetted Organization name that will be combined with information about the individual subscriber e.g. ABC Company, John Doe, US, John.Doe@abc.com . The email address used in the certificate must be one that was issued to an individual from the company that reflected in your registration.

Example of an acceptable email address:

john.doe@globalsign.com

Example of an unacceptable email address:

support@globalsign.com

john.doe@hotmail.com

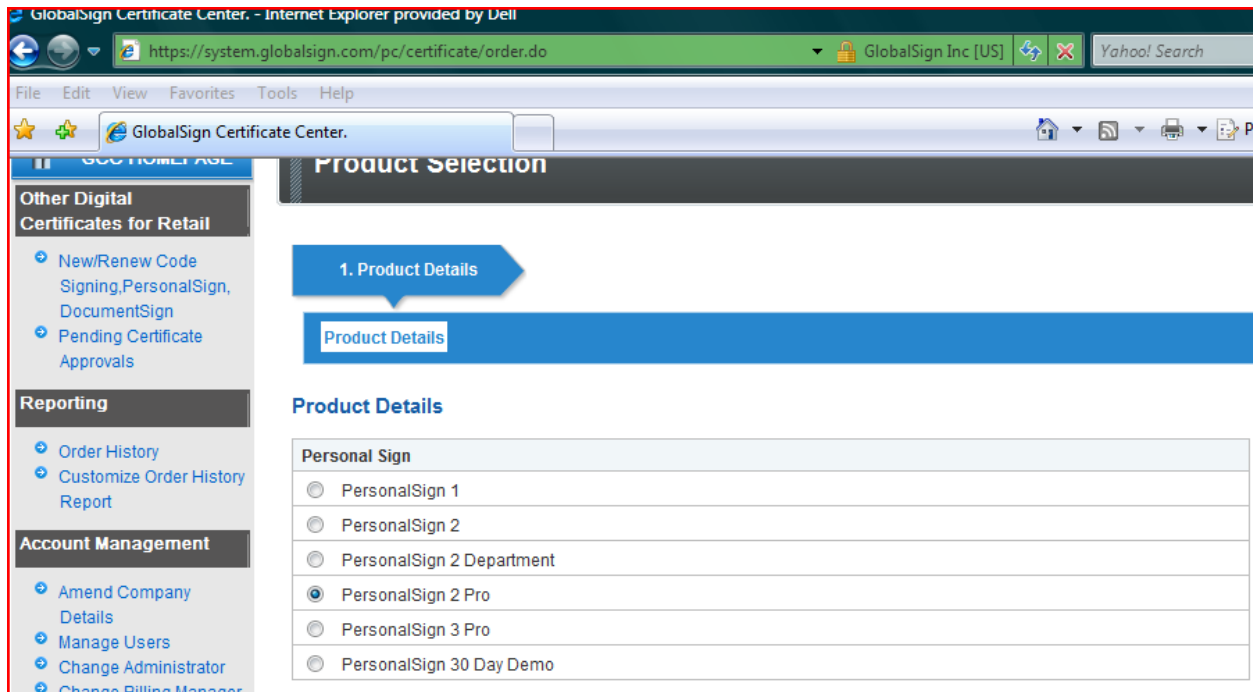
john.doe@gmail.com

3. For best results when ordering and initially installing the Digital ID, please use Firefox. It can be downloaded from <http://www.mozilla.com/>

- a. After installing and launching Firefox, You will need to set the Master Password. Go to Tools > Options > Select Security (located on top menu)>then select Use a master password and enter & confirm a password of your choice > click OK.
4. For assistance with ordering and installing the certificate a user guide can be found at:
http://www.globalsign.com/support/ordering-guides/PersonalSign_GCC_Certificate_Enrollment_Guide.pdf
(If link does not work, manually copy and paste into an internet browser)
5. During the ordering process, you will be asked for a “pickup password”. **PLEASE TRY NOT TO FORGET THIS.** If lost, it cannot be reset. You must place a new order again. You will not be charged for the initial order since it was not completed.
6. Once installed in Firefox, your digital ID needs to be exported and imported into Internet Explorer. See the lower half of <http://www.globalsign.com/support/faq/misc/16.php> for instructions.
7. Once it’s in IE, export it as a .p7b (without the private key) and again as a .pfx (with the private key). NOTE!! Make sure to select “Mark key as exportable” when creating your .pfx file. See <http://www.accessdata.fda.gov/esg/userguide/webhelp/default.htm>, Appendix C. Digital Certificates.
8. Also keep a copy of the .pfx certificate off the computer. If there is a hard drive failure, importing this is the fastest way to obtain the certificate.
9. The .p7b is used for initial Web Trader registration. After the account is created and approved, the .pfx is used for the test submission of documents. See <http://www.accessdata.fda.gov/esg/userguide/webhelp/default.htm>, section 4 FDA ESG Web Interface Electronic Submissions.
10. The FDA ESG will work best with Internet Explorer. See <http://www.accessdata.fda.gov/esg/userguide/webhelp/default.htm> for system requirements.

Common errors when placing a Digital Certificate order for the FDA ESG

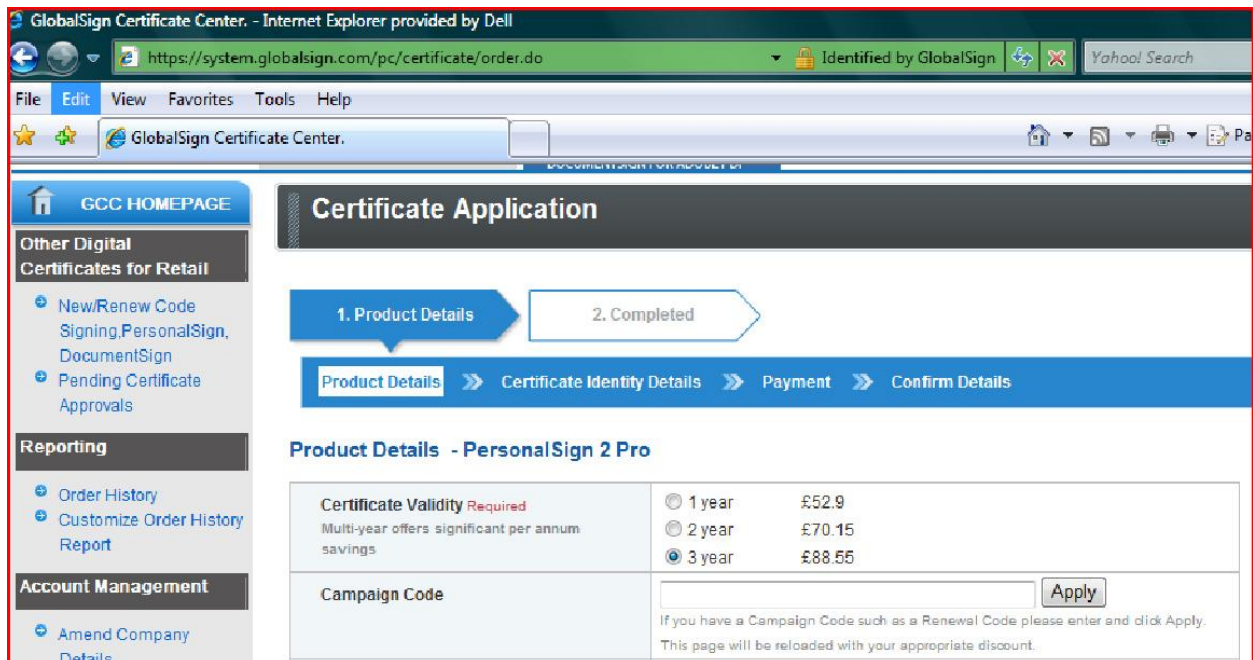
1. The wrong type of certificate was ordered-For the FDA ESG a PersonalSign 2 Pro must be ordered. Please see the instructions below under “Re-Ordering Instructions” to learn how to resolve this error.



The screenshot shows the GlobalSign Certificate Center interface in Internet Explorer. The browser address bar displays <https://system.globalsign.com/pc/certificate/order.do>. The page title is "GlobalSign Certificate Center." The left sidebar contains navigation links under "Other Digital Certificates for Retail", "Reporting", and "Account Management". The main content area is titled "Product Selection" and features a "1. Product Details" step indicator. Below this, a "Product Details" section lists several certificate options:

Personal Sign	
<input type="radio"/>	PersonalSign 1
<input type="radio"/>	PersonalSign 2
<input type="radio"/>	PersonalSign 2 Department
<input checked="" type="radio"/>	PersonalSign 2 Pro
<input type="radio"/>	PersonalSign 3 Pro
<input type="radio"/>	PersonalSign 30 Day Demo

2. The validity period selected was incorrect :(Please choose 3 year validity period) Please see the instructions below under “Re-Ordering Instructions” to learn how to resolve this error.



The screenshot shows the GlobalSign Certificate Center interface in Internet Explorer. The browser address bar displays <https://system.globalsign.com/pc/certificate/order.do>. The page title is "GlobalSign Certificate Center." The left sidebar contains navigation links under "Other Digital Certificates for Retail", "Reporting", and "Account Management". The main content area is titled "Certificate Application" and features a "1. Product Details" and "2. Completed" step indicator. Below this, a "Product Details - PersonalSign 2 Pro" section displays a table of certificate validity options:

Certificate Validity Required	1 year	2 year	3 year
Multi-year offers significant per annum savings.	£52.9	£70.15	£88.55

The "3 year" option is selected. Below the table, there is a "Campaign Code" field with an "Apply" button. A note states: "If you have a Campaign Code such as a Renewal Code please enter and click Apply. This page will be reloaded with your appropriate discount."

3. The wrong company name, person's name, or email address is entered in the "Certificate Identity Details" page: Please make sure this information is entered accurately. Please see the instructions below under "Re-Ordering Instructions" to learn how to resolve this error.

Certificate Identity Details

These details will be vetted and included as the certified identity within your issued Certificate. Make sure the details entered are correct - we will vet the details you include. To assist you, some details will be pre-populated from previous pages or from your GCC account details, you may overwrite these if needed.

Your Name Required	John Smith <small>Specify your First (required), Middle/Initial (optional) and Last Name (required)</small>
Job Title Optional	 <small>Specify your Job Title, such as Manager</small>
Organization Required	GlobalSign Inc. <small>Specify the Organization Registered Name in full, including Inc, Ltd, NV, Plc etc</small>
Locality Optional	Portsmouth <small>Specify the City or Town in which the Organization is Registered</small>
State or Province Optional	New Hampshire <small>Specify State or Province in which the Organization is Registered. For US applications you must specify the State in full</small>
Country Required	United States <small>Specify Country in which the Organization is Registered</small>
Email Address Required	john.smith@abc.com

4. The "Pick Up-Password was forgotten:If the pickup password is forgotten you will need to re-order. Please see the instructions below under "Re-Ordering Instructions" to learn how to resolve this error.

When the vetting is complete we will send an email to the Applicant to pickup the Certificate. For security, please specify a Pickup Password that will be required to release the issued Certificate. NOTE, the usage for this password is different from the GCC login password provided previously, the Pickup Password is used only for this Certificate application.

Pickup Password Required	●●●●●●●● <small>Password must be a minimum of 8 characters. Alpha-numeric values only (A-Z, 0-9)</small>
Pickup Password (re-enter) Required	●●●●●●●●

Reordering: Instructions

If the wrong Digital ID was ordered or it contains incorrect information you will need to cancel the order and re-order the certificate as certificates can not be changed once they have been issued.

.To complete this process, please complete the following steps:

1. Log in and select the PersonalSign signing tab at the top of the page.
2. Select **“Order History”**.
3. Click the **“Search”** button to find your certificate.
4. Once you have found the incorrect certificate, Click **“Edit”**.
5. Click **“Cancel the order and start again”**.
6. Enter the correct information into the **“Certificate information”** page.
7. Since we (GlobalSign) have all the vetting documentation, we can issue the new certificate almost immediately. You will receive a refund for the original certificate in 3 – 5 business days.

Reissuing: Instructions

If the information in the certificate is correct but the private key is lost or not exportable, you can reissue the certificate.

Please follow the following steps to re-issue a certificate:

1. Log in and select the PersonalSign signing tab at the top of the page.
2. Select **“Order History”**.
3. Click the **“Search”** button to find your certificate.
4. Click **“Edit”**.
5. Click **“Reissue”**.
6. The certificate will be available within a few minutes.

*If an original digital ID was used to create the Web Trader test account and the certificate is reissued, contact FDA support so that the new certificate can be used on the account. See Appendix A.

Troubleshooting the FDA ESG Web Interface

<http://www.accessdata.fda.gov/esg/userguide/webhelp/default.htm>

Support

All technical questions should be submitted to our Support Department using the Support Ticket Request form at <http://www.globalsign.com/help>

Please also take a look at our Global Support Center at <http://www.globalsign.com/support/> which contains answers to many commonly asked questions.

Tel: 1-877-GO-SSLHELP (877-467-7543)