

Registration Intake Form

Purpose:

This form should be used to request all necessary information required for registrations. Please fill out one form with all required documents needed for the entirety of the registration.

Instructions:

1. Fill out the date of request, contact name and reason in the subject line (i.e., initial registration, renewal, etc.).
2. Enter company contact information. Make sure the address entered is the same as the mailing address for requests that require documents to be mailed.
3. The SunTech Medical part numbers should be in the format of XX-XXXX-XX.
4. List ALL documents needed for the registration process. If you provide only a portion of the documents at a time, this will delay the registration process.
5. If hard copies are needed, make sure you entered the correct mailing address under company information.
6. If you need more space, fill out additional forms and submit them all at once.
7. To submit this form, send it as an email attachment to regulatoryrequests@suntechmed.com
8. Once all the information has been returned to you, you are required to provide the registration details to us so we are able to keep a record of the registration and track it

NOTE: Many documents can be found on our website at: <https://suntechmed.com/support/document-library>

- For product information such as the User Manual (IFU), click on the product category.
- Regulatory documents are broken up by country.
- Declaration of Conformity and EC Certificate is listed under the EU.
- Certificate to Foreign Government (Free Sales Certificate) is listed under the USA.
- ISO 13485 Certificate is listed under Quality System documents.

Registration Intake Form

Date: [date]

Customer: [name]

Subject: [topic of request]

Company Information:

Name:

Address:

Phone Number:

- What product(s) is/are this for?
- What is the SunTech Medical part numbers?

- What documents are needed? (LOA, labels, test reports, CFG, IFU, safety report, etc.)
 - If need own template, please provide it.

- Do the document needs to be:

○ notarized	Yes	No
○ wet signature	Yes	No
○ on letterhead	Yes	No
○ authenticated	Yes	No

- Hard copies or scanned copies?
- When are the documents needed by? [MM/DD/YYYY]
- What language is required?
- Country being registered
- New Registration or adding products to registration or renewing registration (if renew, when does it expire?)
- Registration record number:
- Registration approval date: [MM/DD/YYYY]

Note: Check website first for product information, such as User Manuals, Regulatory Documents, and Certificates.

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