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. Enter company contact information. Make sure the address entered is the same as the mailing address for requests that require documents to be mailed.
2. Select request type (i.e. new, renewal, additional products).
3. Provide all SunTech Medical part numbers required for registration. Refer to
4. Select ALL documents needed for the registration process. To avoid delays, please ensure all necessary documents are selected and/or provided.
5. If you need more space, fill out additional forms and submit them all at once.
6. To submit this form, send it as an email attachment to regulatoryrequests@suntechmed.com
7. Upon completion of registration, please return registration details to ensure proper tracking and record keeping. (i.e. registration number)
8. If registration details are not provided to SunTech Medical via regulatoryrequests@suntechmed.com or your regulatory assistant within 60 days, you will be contacted to obtain the required documentation. (i.e., registration number)

NOTE: Please check our website first as 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.

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Date:

Country for Registration:

Is a MDR Distributor Agreement in Place? Yes ☐ No ☐

Company Name:

Company Mailing Address:

Request Type: New ☐ Renewal ☐ Update to Current Registration ☐

If Renewal, please provide: Registration Number Expiration Date

Requested Return Date:

*Please note registration requests are fulfilled on a first come first serve basis. Therefore, this is not a guaranteed return date.

Product Selection

Please enter all **SunTech Medical Part Numbers** including part numbers for **ANY** accessory items that require registration. Please note exclusion of required part numbers may delay registration. For product numbers please consult product brochure and/or IFU or contact SunTech Medical customer service at customersupport@suntechmed.com.

Products	**Part Numbers**
CT40	
CT40 Accessories	
Oscar (ABPM)	
Oscar Accessories	
Bravo Mini	
Bravo Accessories	
Tango	
Tango Accessories	
Vet20	
Vet25	
Vet30	
Vet25E	
Vet30E	

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Cuffs	**Part Numbers**
Orbit-K	
Orbit (ABPM)	
Disposable	
All Purpose (APC)	
One-Piece Durable (OPD)	
Veterinary	

Document Selection

Please select all applicable documentation.

Document Requested	Notarized	Wet Signature	On Letterhead	Apostille	Hard Copy	Translation
Declaration of Conformity	☐	☐	☐	☐	☐	☐
Letter of Authentication	☐	☐	☐	☐	☐	
ISO Certificate	☐			☐	☐	
EC Certificate	☐			☐	☐	
IFU						☐
Label(s)						☐
Other:	☐	☐	☐	☐	☐	

***Please provide any necessary templates/declarations to compile the above documentation (i.e. LOAs).**

Test Reports	Biocompatibility	IEC Test Report(s)	Clinical Test Report(s)	Usability Test Report(s)	Stability Test Report(s)	Software Test Report(s)	Other
	☐	☐	☐	☐	☐	☐	☐