In vitro diagnostic medical device questionnaire

ABOUT THIS FORM

Thank you for your interest in SGS certification and notified body services. By filling in this form we will be able to give you a non-binding offer on the assessment and certification of your medical device, quality management system, or both. If you are an existing SGS Fimko client applying for additional certification, please indicate the additions only.

If you are uncertain about the answer to some question you may write "Don't know" and our technical team will contact you for more information. We may also wish to contact you for clarification of some answers, so please ensure that you enter your contact details correctly.

Once you have filled in the form, please return it in electronic format to IVD.devices.fimko@sgs.com or directly to your contact person at SGS. You can also reach us by phone at +358 9 6963 701 or via mail at the following address: SGS Fimko Oy, NB-IVD Devices, Takomotie 8, 00380 Helsinki, Finland.

If you have any questions, please don't hesitate to reach out to us.

QUESTIONNAIRE

SECTION 1: COMPANY INFORMATION	
Company name (Legal entity)	The company is part of a group, please specify:
Website	
Company VAT (TVA) Number	
Economic Operator type	Manufacturer Distributor Importer European Representative
European Single Registration Number(s) (SRN)	*NOTE: If you don't yet have an SRN, please write "TBC" for now, but understand that this identification number is required by EU 2017/746 (see Section 1 of Part A of Annex VI) before a final quote can be supplied or an agreement can be signed. Please see EUDAMED for obtaining the registration number.*
CONTACT PERSON	
Person completing this questionnaire	Please provide your own contact details in case our technical team has questions on the information you filled in this form.
Name	
Position	
E-mail	
Tel	

LANGUAGE	
Quality Management System	In what language are your quality system procedures? English Finnish Other, please specify:
Technical documentation	In what language is your technical documentation? English Finnish Other, please specify:
SITES	
Main site	Please provide details of your main site. If your intended certification site is not your main site, please indicate this under 'Certification site' below.
Address	
Description of activities	
Staff count (FTE)	
Certification site	The certification site is different from the main site, please specify (incl. address, activities and staff count:
Other sites	We have multiple sites to be included in the certification scope. Please specify the address, activities performed, and the number of staff (Full time equivalent, FTE) involved at each site.
Total number of sites	
Total number of staff in the organization	
Total number of staff involved in the activities to be certified	*NOTE: Please also include remote staff and other "off-location" staff members who are expected to work in the certified activities.*

SECTION 2: CERTIFICATION NEEDS			
Quality Management System (QMS) and related standards	Please select the standards you wish to obtain certification against. If you already have current certificates on the standards, please also provide copies of these along with this application.		
	ISO 13485:2016 (e.g., for EU 2017/746)	We already have a valid certificate	We wish to transfer the certificate to SGS
	ISO 9001:2015	We already have a valid certificate	We wish to transfer the certificate to SGS
	ISO 14001:2015	We already have a valid certificate	We wish to transfer the certificate to SGS
	ISO 27001:2022	We already have a valid certificate	We wish to transfer the certificate to SGS
	Other, please specify:		

EU 2017/746 (IVDR) for CE marking of devices	Please select the EU 2017/746 conformity route you wish to obtain certification through. If you wish to use more than one route for your products, please indicate this in Section 4.	
	Annex IX(I, III) QMS and Technical Documentation (II) Route	We already have a valid certificate
	Annex X Type examination and Annex XI Production Quality Assurance route	We already have a valid certificate
	Annex XI: Production Quality Assurance route	We already have a valid certificate
	Article 16: Special route for Importers and Distributors (only for cases in which obligations of manufacturers apply to importers, distributors, or other persons)	We already have a valid certificate
Medical Device Single Audit Program (MDSAP)	If you wish to obtain certification under the Medical Device Single Audit Program (MDSAP) please indicate the MDSAP territories you wish to be certified for below. We will send you a separate questionnaire based on your selections here.	
	Australia (TGA)	Japan (MHLW/ PMDA) / Canada (Health Canada)
	Brazil (ANVISA)	USA (FDA)
Other regulatory jurisdictions	If you wish to obtain certification under other regulatory jurisdictions with us, please indicate the regions below. We will send you a separate questionnaire based on your selections here.	
	EU Legacy Device manufacturers: IVDR Article 110 transition rule follow-ups	Taiwan
	UK (UKCA)	Hong Kong
	Other, please specify:	
SCOPES OF CERTIFICATION (OPTIONAL)		
Quality Management System (QMS)	We have a specific scope statement for the QMS certification. Please elaborate below. Note that you may comment on specific standards and regulations separately if needed.	
IVD medical device (EC)	We have a specific scope statement for the QMS certification. Please elaborate below. Note that you may comment on specific standards and regulations separately if needed.	
PRIOR APPLICATIONS		
Prior applications to EU notified bodies	Have you previously applied with another EU 2017/746 notified body? If yes, please provide a reason for the withdrawal or refusal below.	
	No. We have not applied previously.	
	Yes. Our application has been withdrawn by us. Please elaborate.	
	Yes. Our application has been refused by another notified body. Please elaborate.	
	Yes. Our application for another conformity assessment route and another device/device group is handled by another notified body. Please elaborate.	

CERTIFICATION TRANSFERS (OPTIONAL)			
Transfer certificates to SGS	We wish to transfer a previous in vitro diagnostic medical-device or QMS certificate to SGS Please also provide copies of the current certificates along with this application. Please elaborate below.		
Date of latest audit		Expected next audit	
Requested schedule of transfer			
Reason for transfer	Please tell us the reason for the transfer to SGS.		

SECTION 3: ORGANIZATION DETAILS			
Activities	Please specify which activities are to be covered by this certification.		
	Management	Regulatory	Service provision
	Measurement analysis and improvement	Vigilance	Testing
	Purchasing	Design and development	Installation
	Sales	Production	Servicing
	Other, please specify:		
Off-site activities	Some activities are conducted off-site (other than basic remote work), please specify:		
Shift system	Multiple shifts are used. Please provide the times of the shifts, the number of employees per shift, and a descriptions of the activities per shift:		
Practical arrangements	Interpreters may be required to interview staff (for languages other than English and Finnish)		
OEM	Multiple shifts are used. Please provide the times of the shifts, the number of employees per shift, and a descriptions of the activities per shift:		
SPECIFIC ACTIVITIES (AS APPLICABLE)			
Design & Development	If this activity is to be covered by the certification (see 'Activities'), please select all that apply.		
	Activities include software design		
	Activities include software validation		
Testing	If this activity is to be covered by the certification (see 'Activities'), please select all that apply.		
	Testing is used to demonstrate conformity. If so, please specify how it is performed below.		
Performed by	Staff in-house		
	An accredited testing provider		
	An unaccredited testing provider		
Method(s)	Please also specify if a) a harmonized standard (e.g., IEC 62304, IEC 62366-1, IEC 61010 family of standards) is used and b) whether you also permit alternative methods.		

Production	If this activity is to be covered by the certification (see 'Activities'), please select all that apply.
	Production only of a software-based in vitro diagnostic medical device
	Production of in vitro diagnostic medical devices other than software
	Manufacturing processes or parts of it are outsourced, please specify:
Installation	If this activity is to be covered by the certification (see 'Activities'), please select all that apply.
	Installation activities are performed at customer premises
Clean rooms and sterilization	If this activity is to be covered by the certification (see 'Activities'), please select all that apply.
	Manufacturing is performed in clean rooms
	Other operations are performed within a controlled environment or cleanroom
	In-house sterilization activities, please specify the types of processes:

SUPPLIERS & CONSULTANTS

Suppliers	Please provide details on your use of suppliers in the field of IVD medical devices during the last 3 years. Which of the following apply to your organization?
	No suppliers are used
	Suppliers are used for processes/parts critical to the device or safety. If so, please specify the supplier/subcontractor names and details of outsourced process or activity:
	Suppliers are used for sterilization. If so, please specify the name, address, types of processes and details of their certification/approvals:
	NOTE: SGS will assume that all your critical suppliers have appropriate certification or control for the activities they provide to you, and that no additional audit time is needed to assess them. If they do not, please provide brief details on how you control them.
Consultants (in medical devices)	Please provide details on your use of consultancy and other external services in the field of IVD medical devices during the last 3 years. Which of the following apply to your organization?
	Consultants are used to meet EU requirements for the design, construction, marketing, and/or maintenance of products
	Consultants are used for training
	Consultants are used for internal auditing
Laboratory testing	Laboratory testing services are used (e.g., testing for electro-medical device or software)
Performance evaluation	Performance evaluation services are used

SECTION 4A: IVD MEDICAL DEVICE DETAILS

Nature of devices	Which of the following apply to one or more of your organization's devices?		
Instrument / Reagent	Devices are non-electrical instruments	Devices are electrical instruments	Devices are reagents, controls or / and calibrators
Software	Devices are stand-alone software		
	Devices contain software that is used to control the device		
	Devices contain Artificial Intelligence (AI) technologies		
Self-testing	Devices are intended for self-testing		
Near-patient testing	Devices are intended for near-patient testing		
Companion diagnostic	Devices are intended for companion diagnostic		
Non-viable human, animal or microbiological material or their derivatives	Yes, please specify below		
Sterilization	Devices are supplied in a sterile condition, please specify method(s) below.	Devices are supplied to be sterilized by the end user, please specify supplier and method(s) below.	
Method(s)	Ethylene oxide gas sterilization (EOG)	Low temperature steam and formaldehyde sterilization	
	Moist heat sterilization	Thermic sterilization with dry heat	
	Aseptic processing	Sterilization with hydrogen peroxide	
	Radiation sterilization (e.g., gamma, x-ray, electron beam)	Sterilization method other than specified above	
Connected with another device	The IVD medical devices are intended to be connected with another device. Please specify.		

FOR MANUFACTURERS OF SUBASSEMBLIES & PARTS ONLY (AS APPLICABLE)

Regulated activities	Is the organization contracted to carry out activities that are regulated by a IVD medical device regulation? For example, re-labelling, remanufacturing of other medical devices.	
	Yes	No
Design & Development	Is design and development (D&D) in the scope of the ISO 13485 certification? Note law may permit the exclusion of D&D, for example, in the case low-risk medical devices.	
	Yes	No
Level of assembly	The product is a nearly finished and assembled IVD medical device (i.e., it's intended to be used for a IVD medical purpose and only needs packaging/labelling)	
	The product is intended to be a component/part of a IVD medical device	

SECTION 4A: IVD MEDICAL DEVICE DETAILS

FOR MANUFACTURERS:

Technical Documentation Identification	Device description: Device name + intended use / description	Device class Class A sterile, B, C, D	Classification rules as per EU 2017/746	Basic UDI-DI	Suggested IVR/IVS/IVT	Suggested EMDN

NOTE: For IVDR Annex IX, X or XI certification, SGS may only provide a contract proposal to the legal manufacturer of the medical device, so the entity that will be taking responsibility for its CE Marking under the IVDR.
NOTE: For IVDR certification: IVD MD manufacturers of any Class must have applied for a Basic UDI-DI to apply to that device before the manufacturer applies to SGS Notified Body for conformity assessment under Annex IX.

FOR IMPORTERS/DISTRIBUTORS ONLY (AS PER EU 2017/746 ARTICLE 16):						
Technical Documentation Identification	Device description: Device type + Manufacturer + Device name/model/version (e.g., Transport Ventilator, Manufacturer, Name, Model, Version)	Device class Class A sterile, B, C, D	Basic UDI-DI or UDI-DI	Basic UDI-DI	Article 16(2) (a) provision of information	Article 16(2) (b) changes to packaging

NOTE: Activities may include (choose one or two):

- Article 16(2) (a) provision, including translation, of the information supplied by the manufacturer in accordance with Section 20 of Annex I of IVDR, relating to a device already placed on the market and of further information which is necessary in order to market the device in the relevant Member State.

- Article 16(2) (b) changes to the outer packaging of a device already placed on the market, including a change of pack size.

SECTION 5: ATTACHMENTS

Please list the attachments you provide with this questionnaire, if any, and provide both the filename and short description of why the file is relevant here.

Filename	Description

SUBMITTING THE FORM

Please ensure that you have filled in the form as accurately as possible. Once you have filled in the form, please return it in one of the following ways:

- via submit button at the end of this form,
- in electronic format to IVD.devices.fimko@sgs.com,
- in electronic format directly to your contact person at SGS.

For SGS to be able to give you an accurate quotation for certification services it is important that we identify the scope of the sites and activities to be audited.

On receipt of the completed questionnaire, we will prepare a 'No Obligation' proposal detailing an estimate for the assessment, certification, and other costs. If at any time you would like more information on the questionnaire, or the proposal please don't hesitate to contact us. You can reach us through your SGS contact person or via writing to us as specified in the beginning of this document.

Thank you!

SUBMIT FORM

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When you need to be sure