
# Medical device questionnaire

## COMPLETION GUIDANCE NOTES

1. In order for SGS Belgium (as Notified and Certification Body) 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. Within the SGS Group, different other certification services related to medical devices can be offered (e.g. MDSAP certification, CE certification of In Vitro Diagnostic Devices): please contact your local SGS office for such services.
2. Please answer the enclosed questions as fully as possible mandatory in English (local translation is possible but only indicative for the application), if you do not know the answer to any question please type "don't know" and one of our technical team will contact you to discuss.
3. If you have more than one site to be audited, please provide a list of all the site addresses to be included in the scope, and the activities at each site.
4. Complete one section 6 per devices and add appropriate number of pages of section 6 to cover all the CE certification scope you wish to be cover by SGS. This section (6) should not be completed for devices that don't need a CE certificate from a Notified Body (e.g. devices under self-certification)
5. We may also need to contact you for clarification of your answers so please ensure that you enter your contact details.
6. On receipt of the completed Questionnaire, SGS will prepare and submit a No Obligation proposal detailing the assessment, certification and other costs, and will be followed up by your local Client Manager. In addition to completing this Questionnaire, lodging an official application is to be done by signing the Contract Proposal.
7. Medical Devices Regulation (EU) 2017/745 requires that we carry out unannounced audits on all legal manufacturers, so we ask for information on all your various manufacturing sites (identify links between, and allocation of responsibilities among) and your relevant suppliers and/or subcontractors as potential sites where we may need to audit.
8. If you are an existing client applying for additional certification, please indicate the additions only. For extensions to scope to existing certification please use SGS Notification forms.
9. For MDR 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 MDR.
10. Before applying to SGS Notified Body, Manufacturers must register the information in Section 1 of Part A of Annex VI of the MDR to the Commission Electronic Registration System and obtained a single registration number (SRN) to identify that manufacturer (when the relevant module of EUDAMED will be functional).
11. For MDR certification: 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.
12. If you have already applied with another notified body and withdrawn your application, please inform us about it and about the reason of refusal.
13. Please be aware that this document is intended to collect sufficient data to compile a proposal for certification. Questions e.g. related to non-viable human material should not be interpreted as a confirmation that Notified Body SGS Belgium is able or allowed to certify such devices. The notification scope of SGS Belgium can be found on the official Nando database: http://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=notification.pdf&dir_id=13&ntf_id=275721.
14. The Notified Body SGS Belgium confirms that the information sent will be considered and handled as strictly confidential material.
15. Please return in electronic format or hard copy to your local SGS certification office as shown below:

SGS MD DELIVERING OFFICE:

CONTACT NAME:

PHONE:

EMAIL:

| SECTION 1: CONTACT INFORMATION | | | |
|---|---|---|---|
| Company name (Legal Entity): | | | |
| If company is part of a group, please specify: | | | |
| Website: | | | |
| Company VAT (TVA) Number: | | | |
| Type of Economic operator<br>Legal Manufacturer Authorized representative Importer / Distributor Other, please specify: | | | |
| European Single registration number: | | | |

| Main Address: | |
|---|---|
| Person completing questionnaire (if not manufacturer please explain the relationship with the manufacturer): | |
| E-mail: | Tel No: |

| RESPONSIBLE REGULATORY COMPLIANCE | |
|---|---|
| Name: | |
| Position: | |
| E-mail: | Tel No: |
| **PRIMARY CONTACT PERSON** | |
| Name: | |
| Position: | |
| E-mail: | Tel No: |
| **SECONDARY CONTACT PERSON** | |
| Name: | |
| Position: | |
| E-mail: | Tel No: |

Guidance Notes: Please provide a primary contact person who will be the main contact for arranging audits, and in the case of unannounced audits and urgent regulatory queries. The secondary contact person would be the person who will deputise for the primary contact.

| SECTION 2: THE SERVICES YOU WISH TO RECEIVE FROM SGS |
|---|
| ISO 13485: 2016 (+EN ISO 13485: 2016) – BELAC accreditation |
| ISO 13485: 2016 (+EN ISO 13485: 2016) – UKAS accreditation |
| MDSAP |
| Regulation (EU) 2017/745 for CE Marking of medical devices - *please choose only one conformity route for your certification*<br>Annex IX (Quality Management System & technical documentation)<br>Annex XI (Product Conformity Assessment)<br>*Please Note: SGS only offers Annex XI Part A for Class IIa and Class I* |
| If you do not see the standard or regulatory scheme you require in the list above, please indicate: |

## SECTION 3: ABOUT YOUR ORGANISATION

Are your systems integrated? No Partially Fully

Total number of employees in the organisation?

Total number of employees in the activities to be certified?

Activities: Please list the main processes or activities to be covered by the certification *(for example design, development, injection moulding, clean room assembly, manufacture, warehousing, distribution, servicing, installation)*:

Off –site activities: Do you conduct any activities off site during daytime working hours? Please give detail:

Design: Do you have design responsibility? Yes No

Shift system: Do you operate a shift system? Yes No

If the company operates a shift system, please provide the number of employees per shift, the times of the shifts and descriptions of the activities per shift:

Locations for Multi-site certification *(more than one site under the same Quality Management System)*

How many sites will be covered by the certification in total?

Please provide the list of site addresses and a brief description of activities at each site or group of sites, provide date as well for coming year when an announced visit could not take place (up to a maximum of six week each year):

| SITE NAME & ADDRESS | ACTIVITIES DESCRIPTION & UNAVAILABILITY PERIOD |
|---|---|
| | |
| | |
| | |
| | |

*Please provide a separate table if more than four sites in total.*

Scope of certification *If you have a specific (proposed) scope statement for your certification then please indicate:*

ISO 13485 (BELAC / UKAS)

MDSAP

CE Mark

## ADDITIONAL INFORMATION

Which other certification / registrations does your company hold (if any)? Please attach a copy of certificate(s)

Do you have a dedicated SGS contact (e.g. Client Manager)? If so, please provide their name:

Does SGS currently provide you with any other services? If yes, please provide details:

Are you interested in other certification services from SGS (e.g. MDSAP certification by SGS U.K.)? If yes, please provide details:

| CONSULTANCY AND OTHER SERVICES RENDERED DURING CONCERNING MEDICAL DEVICES LAST 3 YEARS<br>(Please check relevant boxes and give further information below in Section "Details") | | |
|---|---|---|
| Consultancy services in the field of medical devices? | Yes | No |
| Training activities in the field of medical devices? | Yes | No |
| Internal audits? | Yes | No |
| Consultancy services as regards EU requirements for the design, construction, marketing or maintenance of the products under assessment | Yes | No |
| Services related to pre-clinical studies, clinical evaluation, clinical investigations | Yes | No |
| Laboratory testing services (e.g. testing for electro-medical devices) | Yes | No |
| Clinical research | Yes | No |
| Others | Yes | No |

**DETAILS**

Please describe name of organisation / person(s) that are delivering or had delivered services in the field of medical devices for any box that has been check with "Yes":

| SECTION 4: MEDICAL DEVICES GENERAL INFORMATION | | |
|---|---|---|
| Do you want to transfer any medical device or quality system certification? | Yes | No |
| If yes, please provide copies | | |
| Please attach a copy of the certificates: | | |
| Date of last audit: | | |
| Expected date of next audit: | | |
| Reason for transfer to SGS: Cost Service Range of certification Original body ceased operation Other: | | |
| Do you design software (stand alone or embedded) that is used to control your devices? | Yes | No |
| Do your devices incorporate non-viable human or animal material or derivatives? | Yes | No |
| Do your devices incorporate nanomaterials? | Yes | No |
| Do your devices incorporate medicinal products or pharmaceuticals? | Yes | No |
| Do you undertake any operations within a controlled environment or clean room? | Yes | No |
| Do you supply devices in a sterile condition? | Yes | No |
| Do your device incorporate substances absorbed by or dispersed in human body? | Yes | No |
| Do you supply devices that are to be sterilized by the end user? | Yes | No |
| Do you supply implantable devices? | Yes | No |
| Do you supply active medical device that are administering and/or removing a medicinal product? | Yes | No |
| Do you supply devices that are reusable? | Yes | No |
| Do you supply devices that have measurement functions? | Yes | No |
| Do you supply devices without an intended medical purpose? | Yes | No |
| Do you supply Medical Device under Annex XVI condition? | Yes | No |
| Do you supply Class III customer made device? | Yes | No |
| For IVD Devices, is the device intended for self-testing? | Yes | No |
| For IVD Devices, is the device intended for near-patient testing? | Yes | No |

Where you have ticked YES above for any point, please report this information into the corresponding device specific characteristic* in section 6 below and detail it (by example for sterile device explain which type of sterilisation is used Eto, Steam, ..).

In-house or 3rd Party testing for electro-medical devices: Do you use harmonized standards such as the EN 60101 family for your device to show presumption of conformity? Is testing carried out in-house, or in an unaccredited 3rd party test house (no accreditation to ISO 17025) or at a 3rd party accredited test house? Do you use any other alternative methods instead? Please give details:

Sterile devices: If you operate sterilization processes on site, please give details of the types of processes:

Sterilization subcontractor: If you use a sterilization sub-contractor please give the name & address of the sub-contractor, the types of processes and details of their certification or approvals:

Reusable product: Please give details of the aspect relating to the reuses of the device:

Devices sterilised by end user: Please give details of the types of sterilization process to be used by the end user:

Other relevant suppliers and/or subcontractors: If there are any other outsourced processes that may impact general safety and performance requirement of your product (such as design, manufacture of the device or components, sterilization, packing, cleanroom assembly, coating, when the conformity of finished devices is significantly influenced by the activity of the supplier , etc), please give their company names and details of outsourced process or activity:

Approval of relevant suppliers and/or subcontractors: SGS will assume that all your relevant sub-contractors and suppliers have appropriate certification (CE certification or accredited ISO13485 or GMP certificate relevant to the activities subcontracted by your organisation) and you apply controls for the activities they provide for you, and that no additional audit time is needed to assess them.

If they do not, please provide details:

*Please use an additional page if required*

## SECTION 5: PRODUCT DESCRIPTION

*(Include as much of this page as you have product that need to be covered by CE certification)*

Device name *(including trade names of this device)*:

Short Description of the device:

Basic UDI-DI:

Intended use:

Device Classification

Device Class:

Applicable rules (annex VIII MDR (EU) 2017/745):

Specific characteristic * (As per selection in section 4):

Choice of conformity assessment route according to MDR 2017/745 *(please choose only one conformity route for your certification)*:

Annex IX (Quality Management System & technical documentation

Annex XI (Product Conformity Assessment)

Confirm that full TD is available on English and in electronic format Yes No

MDS codes (indicate the specific features of devices: Each device can bear several MDS codes (under the general rule – all applicable codes) or could have no such codes assigned at all.)

MDS 1001 Devices incorporating medicinal substances

MDS 1003 Devices manufactured utilising tissues or cells of animal origin, or their derivatives

MDS 1004 Devices which are also machinery as defined in point (a) of the second paragraph of Article 2 of Directive 2006/42/EC of the European Parliament and of the Council

*MDS 1005 Devices in sterile condition

MDS 1006 Reusable surgical instruments

*MDS 1007 Devices incorporating or consisting of nanomaterial

MDS 1008 Devices utilising biologically active coatings and / or materials or being wholly or mainly absorbed or locally dispersed in the human body or are intended to undergo a chemical change in the body

MDS 1009 Devices incorporating software / utilising software / controlled by software, including devices intended for controlling, monitoring or directly influencing the performance of active or active implantable devices

MDS 1010 Devices with a measuring function

MDS 1011 Devices in systems or procedure packs

MDS 1012 Products without an intended medical purpose listed in Annex XVI to Regulation (EU) 2017/745

MDS 1013 Class III custom-made implantable devices

MDS 1014 Devices incorporating as an integral part an in vitro diagnostic device

MDT codes (indicate the technological processes utilized during the manufacturing of the device: Each device should have at least one MDT code assigned after MDA/MDN codes are assigned)

MDT 2001 Devices manufactured using metal processing

MDT 2002 Devices manufactured using plastic processing

MDT 2003 Devices manufactured using non-metal mineral processing (e.g. glass, ceramics)

MDT 2004 Devices manufactured using non-metal non-mineral processing (e.g. textiles, rubber, leather, paper)

MDT 2005 Devices manufactured using biotechnology

MDT 2006 Devices manufactured using chemical processing

MDT 2007 Devices which require knowledge regarding the production of pharmaceuticals

MDT 2008 Devices manufactured in clean rooms and associated controlled environments

*MDT 2009 Devices manufactured using processing of materials of human, animal, or microbial origin. Outside of human tissue

MDT 2010 Devices manufactured using electronic components including communication devices

MDT 2011 Devices which require packaging, including labelling

*MDT 2012 Devices which require installation, refurbishment

*MDT 2013 Devices which have undergone reprocessing

**EMDN (EUROPEAN MEDICAL DEVICE NOMENCLATURE)**

**TECHNICAL DOCUMENTATION (TD)**

Name & reference:

| | | |
|---|---|---|
| Confirm that full TD is available on English and in electronic format | Yes | No |
| Is the technical documentation covering more than one (1) product? | Yes | No |

If yes, please list all product covered and grouping rational:

**DECLARATION OF CONFORMITY**

| | | |
|---|---|---|
| Confirm that draft of an EU declaration of conformity in accordance with Article 19 and Annex IV for the device model covered by the conformity assessment procedure | Yes | No |

## SECTION 6: DECLARATIONS AND CONFIRMATION

*(according to MDR Article 53 of MDR 2017/745)*

UNDERSIGNED LEGALLY REPRESENTING LEGAL MANUFACTURER DECLARES:

| | | |
|---|---|---|
| Is an application lodged in parallel with another Notified Body for the same device-related conformity assessment procedure? | Yes | No |
| Has an application with another notified body been withdrawn (by you as the applicant) prior to the notified body's decision regarding the conformity assessment. | Yes | No |

If 'no' on the question above, please provide information about the previous application for the same conformity assessment that has been withdrawn.

Detail the Notified Body whose application is withdrawn.

| | | |
|---|---|---|
| Has any previous application with another notified body been refused (by that Notified Body) for the same conformity assessment. | Yes | No |

If 'no' on the question above, please provide information about the previous application for the same conformity assessment that has been refused by that notified body.

Detail the Notified Body who refused the application.

## CONFIRMATION *(by the legal manufacturer)*

The information in this pre-application form is true and complete. Incomplete, incorrect or misleading information may lead later to an application that may be refused by the Notified Body or change in provided service and price.

Signature

Name and date

Position

| **SECTION 7: ATTACHED DOCUMENTS**<br>*Please provide all documents as per Annex IX section 2 required for your application.* | |
|---|---|
| **NEXT DOCUMENTS ARE ATTACHED TO THIS QUESTIONNAIRE** | |
| Name / Number | DESCRIPTION |
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WHEN YOU NEED TO BE SURE

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