Medical Device Questionnaire

***** FOR USE UNDER MDR ONLY *****

COMPLETION GUIDANCE NOTES

1. For SGS Belgium (as Notified and Certification Body) to be able to give you an accurate quotation for certification services, we must 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 Product Information Questionnaire (LPMDREG1010) per device to cover all of the CE certification scope that you wish to be covered by SGS.
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 obtain 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 the reason for 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 the company is part of a group, please specify:

Website:

Company VAT (TVA) Number:

Type of Economic operator

☐ Legal Manufacturer

☐ Authorized representative

☐ Importer/distributor

☐ Other, please specify:

European Single registration number:

Main Address

Street: Nr:

Postal code: Place: Country:

Person completing questionnaire (if not manufacturer, please explain the relationship with the manufacturer):

E-mail: Tel No:

Name Responsible regulatory compliance:

Name: Surname:

Position: E-mail: Tel No:

Primary Contact Person:

Name: Surname:

Position: E-mail: Tel No:

Primary Contact Person:

Name: Surname:

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 deputize 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

☐ Annex IX (Quality Management System & technical documentation)

☐ Annex XI (Product Conformity Assessment)
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 ORGANIZATION

Are your systems integrated? ☐ No ☐ Partially ☐ Fully

Total number of employees in the organization?

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 molding, 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 a date as well for the coming year when an announced visit could not take place (up to a maximum of six weeks 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 certifications/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 CONCERNING MEDICAL DEVICES IN THE LAST 3 YEARS (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 the name of the organization/person(s) that are delivering or had delivered services in the field of medical devices for any box that has been checked 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

Does your design software (standalone 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 devices incorporate substances absorbed by or dispersed in the 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 devices 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 Devices under Annex XVI condition?	☐ Yes	☐ No
Do you supply Class III customer-made devices?	☐ 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 sterilization 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 sterilized 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 requirements 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 organization) 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: 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 'yes' 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 'yes' 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

Date Position

SECTION 6: ATTACHED DOCUMENTS

Please provide all documents as per Annex IX Section 2.1 required for your application.

NEXT DOCUMENTS ARE ATTACHED TO THIS QUESTIONNAIRE

Name/number	Description