Medical Device Questionnaire

***** FOR PRODUCTS WHERE CE CERTIFICATION BY NOTIFIED BODY SGS, ACCORDING TO REGULATION (EU) 2017/745, IS SOUGHT *****

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, other medical device-related certification services can be offered (e.g. MDSAP certification and CE certification of in vitro diagnostic devices). Please contact your local SGS office for such services or consult our medical devices web page https://www.sgs.com/en/service-groups/medical-devices and our Information Center https://www.sgs.com/en/our-services/health-and-nutrition/health-science/eu-medical-devices-regulations-information-center to obtain more information about conformity assessment.
2. Please answer the enclosed questions as fully as possible and in English (local translation is possible but only indicative for the application). If you do not know the answer to any of the questions, please type "don't know" and one of our technical team will contact you to discuss.
3. Please complete the List of Relevant Subcontractors and Suppliers form (available on our website). Then, send it to your local SGS office with this questionnaire.
4. 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.
5. Please complete one Product Information Questionnaire (available on our website) per device/device category to be certified under Medical Device Regulation (EU) 2017/745. Then, send it to your local SGS office with this questionnaire.
6. For distributor and importer (certification according to MDR Article 16), no Product Information Questionnaire is required and the relevant MDA/MDN code shall be identified in this questionnaire.
7. We may also need to contact you for clarification of your answers, so please ensure that you enter your contact details.
8. Upon receipt of the completed questionnaires, SGS will submit to you a non-committal contract proposal, detailing the assessment, certification and costs that 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.
9. Medical Device Regulation (EU) 2017/745 requires us to carry out unannounced audits on all legal manufacturers. Therefore, we ask you to provide us with 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.
10. If you are an existing client applying for additional certification, please indicate the additions only. For extensions to the scope of existing certification, please use the SGS Notification of Changes or Regulatory Action form (available on our website).
11. Please note that 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.
12. 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).
13. For MDR certification, manufacturers of any class must have applied for a Basic UDI-DI for their medical device before applying to SGS Notified Body for conformity assessment under Annex IX and Annex XI.
14. If you have already applied with another Notified Body and withdrawn your application, please inform us and include the reason for withdrawal. If your application was refused by another Notified Body, please inform us and include the reason for refusal.
15. The Notified Body SGS Belgium confirms that the information sent will be considered and handled as strictly confidential material.
16. Please return this questionnaire to your local SGS certification office.

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 (ESR/SRN):

Main address[1]

Street: Nr:

Postal code: Place: Country:

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

Name: Surname:

Position: Email: Tel no:

The person responsible for regulatory compliance:

Name: Surname:

Position: Email: Tel no:

Primary contact person:

Name: Surname:

Position: Email: Tel no:

Secondary contact person:

Name: Surname:

Position: Email: Tel no:

EU authorized representative (for a manufacturer outside of the EU):

Name: Tel no:

Address Email:

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 the primary contact.

SECTION 2: THE SERVICES YOU WISH TO RECEIVE FROM SGS

ISO 13485:2016 (+EN ISO 13485:2016) – UKAS accreditation

UK MDR 2002 (UKCA)

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 and technical documentation)

Annex XI (product conformity assessment)

Please note: SGS only offers Annex XI Part A for Class IIa and Class I devices

Article 16 certification for distributor or importer only

Article 117 assessment of medicinal product incorporating a medical device for pharmaceutical company

If you do not see the standard or regulatory scheme you require in the list above, please indicate:

[1] The address of the legal manufacturer: street/road, number/house/floor, postal code, city, state/region and country. Not all of these details may be part of the registered address in the country where the manufacturer or authorized representative has his registered place of business. For instance, a postal code may not exist in a particular Member State or a floor number may not be relevant and therefore cannot be included. On the other hand, a standard postal address that will identify the location of the manufacturer in that Member State is acceptable (a postal box/post office addresses are therefore not acceptable as it would not identify the specific location of the manufacturer).

SCOPE OF CERTIFICATION

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

ISO 13485 (UKAS)	MDSAP	UK MDR 2002 (UKCA)	CE Mark

SECTION 3: ABOUT YOUR ORGANIZATION

Are your systems integrated? No Partially Fully

Total number of full-time employees (FTE) in the organization?

Total number of full-time employees (FTE) in the activities to be certified? for ISO 13485 certification for MDR certification

Total number of medical devices to be certified (sales reference):

Activities: Please list the main processes or activities to be covered by the certification (*for example, designing, development, injection molding, cleanroom assembly, manufacturing, warehousing, distribution, servicing and installation*):

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

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 full-time employees (FTE) per shift, the times of the shifts and descriptions of the activities per shift:

Shift times FTE per shift Description of activities

LOCATIONS FOR MULTISITE 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, as well as dates for the coming year when an announced visit could not take place (up to a maximum of six weeks each year):

Site name and address

Activities description

Unavailability period

Number of employees

ADDITIONAL INFORMATION

Which other certifications/registrations does your company hold (if any)? Please attach a copy of certification(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 SGS certification services (e.g. MDSAP, UK MDR 2002 [UKCA], IVDR)? If Yes, please provide details:

For Article 16 certification, please list below all applicable codes from Impl. Act 2017/2185:

CONSULTANCY AND OTHER SERVICES RENDERED CONCERNING MEDICAL DEVICES IN THE LAST THREE YEARS (Please check relevant boxes and give further information below in the 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 preclinical 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, for any box that has been checked with Yes, the name of the organization/person(s) that are delivering or have delivered services in the field of medical devices:

SECTION 4: TRANSFER OF MEDICAL DEVICE OR QUALITY SYSTEM CERTIFICATION

Do you want to transfer any medical device or quality system certification? Yes No

If yes, 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:

CONFIRMATION (BY THE LEGAL MANUFACTURER):

The information in this application form is true and complete. Incomplete, incorrect or misleading information may lead to the refusal of your application later in the process by the Notified Body, or may lead to a change in provided service and price.

Signature: Name:

Date: Position:

ATTACHED DOCUMENTS Please provide all documents as per Annex IX Section 2.1 required for your application.	
THE NEXT DOCUMENTS ARE ATTACHED TO THIS QUESTIONNAIRE	
Name/number:	Description:
Please use an additional sheet if necessary	