Medical device questionnaire

*** For products where CE certification by SGS Belgium NV (Notified Body 1639), according to Regulation 2017/745 or Regulation (EU) 2017/746, is sought ***

COMPLETION GUIDANCE NOTES

1. For SGS Belgium NV (NB 1639) 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, UKCA, ISO 13485 certification). To obtain more information about possible conformity assessment routes, please contact your local SGS Delivering Office or visit our Medical Devices Regulatory Compliance website https://www.sgs.com/en/our-services/business-assurance/medical-devices-regulatory-compliance
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 any uncertainties.
3. Please complete the List of Relevant Subcontractors and Suppliers (available on our website). Subsequently, send it to your local SGS Delivering 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 or In Vitro Diagnostic Medical Device Regulation (EU) 2017/746 and/or one System and Procedure Pack Product Information Questionnaire to be certified under Medical Device Regulation (EU) 2017/745. Subsequently, send it to your local SGS Delivering Office with this questionnaire.
6. We may also need to contact you for clarification of your answers, therefore please ensure that your correct contact details are provided.
7. Upon receipt of the completed questionnaires, SGS Belgium NV (NB 1639) will conduct a pre-application review before sending you a non-committal contract proposal, detailing the assessment, certification and costs that will be followed up by your local client manager. At this stage, SGS Belgium NV (NB 1639) considers your application officially lodged.
8. Medical Device Regulation (EU) 2017/745 and Regulation (EU) 2017/746 require us to carry out unannounced audits on all legal manufacturers. We therefore ask you to provide us with information on all your various manufacturing sites (please identify links between and allocation of responsibilities among) and your relevant suppliers and/or subcontractors, as potential sites where we may need to audit.
9. 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).
10. Please note that for MDR/IVDR 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/IVDR.
11. Before applying to SGS Belgium NV (NB 1639), manufacturers must register the information in Section 1 of Part A of Annex VI of the MDR or IVDR 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).
12. Manufacturers of any class must have applied for a Basic UDI-DI for their medical device before applying to SGS Belgium NV (NB 1639) for conformity assessment under Annex IX and Annex XI.
13. 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.
14. SGS Belgium NV (NB 1639) confirms that the information sent will be considered and handled as strictly confidential material.
15. Please return this questionnaire to your local SGS Delivering 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 (SRN):
MAIN ADDRESS:[1] Street: No.: 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 for the primary contact.

[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).

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

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 22 Certification for Systems and Procedure Packs

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

REGULATION (EU) 2017/746 FOR CE MARKING OF IN VITRO DIAGNOSTIC MEDICAL DEVICES

Annex IX (Quality Management System and Technical Documentation)

Annex XI (Product Conformity Assessment).
Please note: SGS only offers Annex XI for class A sterile devices

Article 16 Certification for distributor or importer only

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

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 (MDR): CE Mark (IVDR):

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?	Total number of medical devices to be certified (sales reference):
	for ISO 13485 certification for MDR certification for IVDR certification	

Activities:	Off-site 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):	*Do you conduct any activities off-site during daytime working hours? Please provide 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 unannounced visit could not take place (up to a maximum of six weeks each year):

Site name & address:	Activities description:	Unavailability period:	Number of employees:

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

ADDITIONAL INFORMATION

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

Are you interested in other SGS certification services (e.g. MDSAP, UK MDR 2002 [UKCA])?
If yes, please provide details:

Do you have a dedicated SGS contact (e.g. client manager)?
If yes, please provide their name:

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

CONSULTANCY AND OTHER SERVICES CONCERNING MEDICAL DEVICES RECEIVED BY YOUR ORGANIZATION IN THE PAST 3 YEARS.

In order to assure the impartiality and objectivity of your conformity assessment, please provide us with information on services your organization has received from external contractors. This information will be used by SGS NB 1639 to ensure the absence of conflict of interest during planning and execution of activities associated with your certification process.
(Please check relevant boxes and give further information below in the section "Details")

Consultancy services in the field of medical devices, in vitro diagnostic medical devices or active implantable medical devices?	Yes	No	Services related to preclinical studies, clinical/performance evaluation, clinical investigations, performance studies?	Yes	No
Training activities in the field of medical devices, in vitro diagnostic medical devices or active implantable medical devices?	Yes	No	Laboratory testing services (e.g. testing for electro-medical devices)?	Yes	No
Consultancy services as regards EU requirements for the design, construction, marketing or maintenance of the products under assessment?	Yes	No	Clinical research?	Yes	No
			Internal audits?	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:

Date:

Name:

Position:

ATTACHED DOCUMENTS

Please provide all documents as per Annex IX Section 2.1 of MDR (EU) 2017/745 or IVDR (EU) 2017/746 required for your application.

Next documents are attached to this questionnaire.

Name/number:	Description:

Please use an additional sheet if necessary.

When you need to be sure