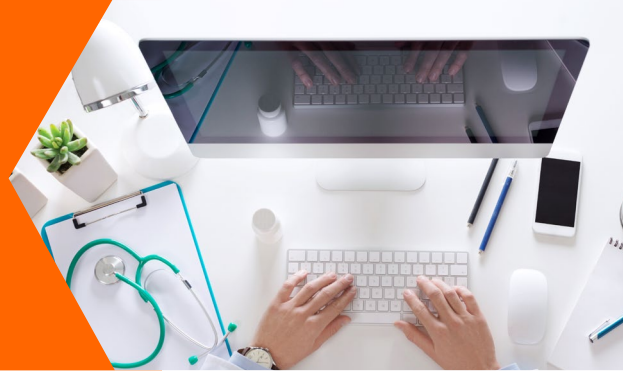
Product information questionnaire

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



This document should not be completed for devices that don't need a CE certificate from a Notified Body (e.g. devices under self-certification)

This document is not applicable for certification under MDD 93/42/EEC

COMPLETION GUIDANCE NOTES FOR CLIENTS/APPLICANTS

1. PART A is to be completed by the client/applicant, PARTS B and C are to be completed by SGS
2. For SGS to be able to give you an accurate quotation for certification services, we must identify the products to be certified.
3. One form must be completed, mandatory in English, for each device/ device category to be certified under Medical Devices Regulation (EU) 2017/745
4. Please answer the enclosed questions as fully as possible, if you do not know the answer to any question please type "don't know" and one of our medical device specialists will contact you to discuss.
5. 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.
6. Please attach the product information questionnaire to the Medical Device Questionnaire
7. Please attach additional information concerning this device/ device category (flyer, commercial brochure)
8. Please attach a draft of an EU Declaration of Conformity for the device model to be certified.
9. Please be aware that this document is intended to collect sufficient data to compile a proposal for certification. Questions e.g. related to devices containing tissue or cells of human origin or derivatives 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
10. According to MDR (EU) 2017/745, SGS will perform unannounced audits, at any of the sites of the legal manufacturer or involved subcontractor/ suppliers, so we ask for information on all your sites and your relevant suppliers and/or subcontractors as potential sites where we may need to audit.
11. Completing this document is only informative and is not considered (officially) lodging an application. Lodging an application is done by signing a contract proposal.
12. The Notified Body SGS Belgium confirms that the information sent will be considered and handled as strictly confidential material.

COMPLETION GUIDANCE NOTES FOR SGS DELIVERING OFFICE

1. PART A should be reviewed by the Delivering Office to make sure the information is complete and sufficient to understand the device/device category and the QMS processes to design, develop, manufacture and/or distribute the device.
2. SGS Delivering office needs to make sure the legal manufacturer, completed and signed document, as well as the completed Word document, are available.
3. PART B and PART C should be fully prepared/completed by the Delivering SGS Office, but approval will be done by the Notified Body SGS Belgium.

Part A – to be completed by the client

SECTION 1: CONTACT INFORMATION	
Company name (Legal Manufacturer):	
Company address[1] (registered place of business):	
European Single Registration Number (ESR/SRN):	
Person completing questionnaire:	
Person responsible for compliance:	
E-mail:	Tel No:

SECTION 2: PRODUCT DESCRIPTION		
Device name (including trade names of this device)		
Description of the device (please attach a technical product description on one or two pages: this includes preferably a drawing, picture, or photo)		
Basic UDI-DI		
Intended use & Clinical Claims (including, where applicable, clinical indications and intended patient population)		
Qualification of this device according to the definitions in Regulation (EU) 2017/745	☐ medical device for human use ☐ accessory of a medical device for human use ☐ Annex XVI product without an intended medical purpose	
	☐ custom-made device ☐ investigational device	
Justification of why this device is considered a medical device, accessory or and annex XVI device according to the Regulation (EU) 2017/745		
Classification (only one selection possible)	☐ I sterile ☐ I reusable	☐ I measuring ☐ I sterility + measuring
	☐ IIa ☐ IIb implantable	☐ IIb conducting medicinal product ☐ IIb other
	☐ III incorporating medicinal substance ☐ III containing animal product derivatives	☐ III other
	☐ Annex XVI product without an intended medical purpose	
Specific characteristics (multiple selections are possible)	☐ transient use ☐ long-term use ☐ invasive via body orifice ☐ active ☐ diagnosis use and monitoring ☐ in contact with central nervous system	☐ short term use ☐ implantable ☐ surgically invasive ☐ therapeutic use ☐ in contact with central circulatory system ☐ in contact with injured skin or mucus
Justification of classification (+ applied rule) according to Annex VIII of MDR 2017/745		

[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).

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)

Coding of the device according to the European Regulation 2017/2185 Codes (for the device to be certified)[2] Select applicable appropriate codes from the drop-down list These codes are mandatory to be selected by the applicant	MDA/MDN code (based on the intended purpose and design of the device: higher codes should be applied since only one MDA/MDN code can be assigned to the particular device.) Choose an item. Choose an item. 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.) Choose an item. Choose an item. Choose an item. 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) Choose an item. Choose an item. Choose an item.

European MD nomenclature[3]	☐ Not yet determined	Code	Description
Other internationally recognized medical device nomenclature code and related description (e.g. Global Medical Device Nomenclature (GMDN) code and related description)	☐ Not applicable ☐ next nomenclature is used:	Code	Description

The device incorporates tissue or cells of animal origin or derivatives (e.g. gelatine, collagen) ☐ Yes ☐ No
Please detail

The device incorporates tissue or cells of human origin or derivatives (e.g. gelatine, collagen) ☐ Yes ☐ No
Please detail

The device incorporates or consists of nanomaterial. ☐ Yes ☐ No
Please detail

The device incorporates medicinal products or pharmaceuticals ☐ Yes ☐ No
Please detail

Does your device incorporate substances absorbed by or dispersed in the human body? ☐ Yes ☐ No
Please detail

The device is manufactured in a controlled environment or clean room ☐ Yes ☐ No
Please detail

This device is sterile ☐ Yes ☐ No

Sterilization is done 'in-house' ☐ Yes ☐ No ☐ not applicable

Sterilization process: ☐ Aseptic process ☐ Ethylene Oxide ☐ Gamma irradiation
☐ Moist heat (steam) ☐ Gas plasma (dry heat) ☐ Electron beam

Remarks

[2] https://eur-lex.europa.eu/eli/reg_impl/2017/2185/oj
[3] https://webgate.ec.europa.eu/dyna2/emdn/

CLINICAL EVALUATION CONSULTATION PROCEDURE (CECP)

Is the device class III implantable, or class IIb for Administration and/or Removal of Medicinal Products (ARMP)?

☐ Yes ☐ No

Is the device a modification of a device already marketed by the same manufacturer for the same intended purpose, and do you consider that the modifications do not adversely affect the benefit-risk ratio of the device?

☐ Yes ☐ No

Have the principles of the clinical evaluation of the device type or category been addressed in a Common Specification (CS) referred to in Article 9 of the MDR, and do you consider that the clinical evaluation is in compliance with the relevant CS for clinical evaluation of that kind of device?

☐ Yes ☐ No

If the device is class III implantable, or class IIb ARMP, but you believe it is exempt from CECP, please provide your rationale here

SECTION 3: TECHNICAL DOCUMENTATION (INCLUDING CLINICAL EVALUATION)

Name or number of the Technical Documentation

Confirmation that the full Technical Documentation is in English ☐ Yes ☐ No

A draft of an EU declaration of conformity (in accordance with MDR 2017/745 Article 19 and Annex IV) for the device model covered by this pre-application, is added ☐ Yes ☐ No

If 'no', confirm such draft EU declaration of conformity will be added in the application (as required by MDR 2017/745)

☐ Yes ☐ No

TECHNICAL DOCUMENTATION:

Structure: The Technical Documentation is following Annex II & III[4]

☐ Yes ☐ No

CLINICAL EVALUATION:

performed according to requirements of MEDDEV 2.7.1 (revision 4 or more recent if publicized) and annex XIV part A of MDR

☐ Yes ☐ No

Please detail

Documentation completed and available for submission

☐ Yes ☐ No

SECTION 4: PROCESS (OF THE PRODUCT CONCERNED)

Confirmation that the product-related QMS (e.g., registrations, records, procedures) is only in English: ☐ Yes ☐ No

Specify if the QMS contains non-English documents without a (validated) English version. (The acceptance of such application is at the discretion of the Notified Body):

Please attach a process flow chart, including the identification of the different involved sites and the outsourced processes.

Process flow chart attached: ☐ Yes ☐ No

MULTISITE ACTIVITIES:

Address	Brief description of the activities related to the product above

[4] http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-190321-nivd-dma-toc-n9.pdf

Use of this new, but internationally agreed structure to structure, the Technical Documentation will make review by Notified Bodies and authorities easier as well as updating by manufacturers. It may result in less time-consuming updates, reviews and may result in fewer non-conformities. It is expected that this structure will become officially recommended in E.U. or even mandatory.

OUTSOURCED PROCESSES: PROCESSES PERFORMED BY A SUBCONTRACTOR OR SUPPLIER			
Name and address of relevant subcontractor and/or supplier	Brief description of the activities related to the product above	Relevant (e.g. ISO13485) certification Please attach a copy of certificate(s)	Methods to control the subcontracted activities

SECTION 5: ATTACHMENTS	
Next documents are attached (add more lines if needed):	
Document title:	Content:
1.	
2.	
3.	
4.	

SECTION 6: DECLARATIONS AND CONFIRMATION (according to MDR Article 53 of MDR 2017/745)	
Undersigned declares:	
• no application is or will be lodged in parallel with another Notified Body for the same device-related conformity assessment. Please detail if any answer is 'Not confirmed' Detail the Notified Body.	☐ confirmed ☐ Not confirmed
• no application with another notified body is withdrawn (by you as the applicant) prior to the notified body's decision regarding the conformity assessment. If 'Not confirmed' 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.	☐ confirmed ☐ Not confirmed
• no previous application with another notified body is refused (by that Notified Body) for the same conformity assessment. If 'Not confirmed' 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.	☐ confirmed ☐ Not confirmed
• that this pre-application form is completed and signed by the legal manufacturer	

CONFIRMATION (BY THE LEGAL MANUFACTURER): (please send the completed document in Word and signed document in PDF)

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.

Signature

Name

Date

Position

PART B pre-application review technical

TO BE COMPLETED BY SGS (APPROVAL BY NB169)

Notified Body SGS Belgium accepts the device described above as • medical device (for human use), • accessory for medical devices, or • product listed in MDR 2017/745 Annex XVI for which MDR is applicable (based on the preliminary information above) Justification in case of 'No' is selected:		☐ Yes ☐ No	
Notified Body SGS Belgium accepts the classification of the device described above. (based on the preliminary information above) Justification in case of 'No' is selected:		☐ Yes ☐ No	
Notified Body SGS Belgium confirms the applied for conformity assessment route is applicable to the device described above (based on the preliminary information above) Justification in case of 'No' is selected:		☐ Yes ☐ No	
Notified Body SGS Belgium confirms that • the applied for conformity assessment route (as described above) • the device to be certified (as described above) is covered by Notification of the Notified Body SGS Belgium, N° 1639, as referenced in LPP MDREG.00 (scope publicized in the Nando database under control of the European Commission) (based on the preliminary information from the manufacturer) Justification in case of 'No' is selected:		☐ Yes ☐ No	
Is the device as described above acceptable for certification assessment by the Notified Body SGS Belgium		☐ Yes ☐ No	
Justification of decision (In case of a refusal, the motivation needs to be clearly documented)			
Estimation of time needed for initial and renewal review of the Technical Documentation by a Product Assessor according to LPMDREG1022.	☐ Default time:		
If a non-default assessment time is specified, this needs to be justified (e.g. innovative device)	☐ Specific:	Justification:	Estimated time:
Is an additional Technical Expert necessary?		☐ Yes ☐ No (skip the other questions in this table)	
Which specialization is required? (e.g., electro-medical engineer, radiation physicist)			
Estimation of time needed for technical project management.		Estimated time:	Justification (optional):
Estimation of time needed by the Technical Expert.		Estimated time:	Justification (optional):
Approved by CWS approver		Date	

PART C pre-application review technical

TO BE COMPLETED BY SGS (APPROVAL BY IHC)

Estimation of time needed for clinical oversight of the technical documentation (as per LPMDREG1022) If a non-default assessment time is specified, this needs to be justified (e.g. innovative device, many different clinical claims…)		
Is an external Clinical Expert necessary?	☐ Yes ☐ No (skip the other questions below)	
Which field of expertise is required? (e.g., cardiologist, neurologist, dermatologist)		
Estimation of time needed for clinical project management.	Estimated time:	Justification (optional):
Estimation of time needed by the clinical expert.	Estimated time:	Justification (optional):
CLINICAL EVALUATION CONSULTATION PROCEDURE (CECP) Does SGS consider that the device is subject to the CECP?	☐ Yes ☐ No	
Approved by IHC	Date	