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 do not need a CE certificate from a Notified Body (e.g. devices under self-certification).

COMPLETION GUIDANCE NOTES

1. PART A of this questionnaire is to be completed by the client/applicant, PARTS B and C are to be completed by SGS.
2. For SGS to give you an accurate quotation for our certification services, we must identify, in detail, all the products that need to be certified.
3. Please answer the enclosed questions as fully as possible and in English. 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.
4. One form has to be completed for each device/device category to be certified under Medical Device Regulation (EU) 2017/745. This form shall only cover multiple devices if they are covered by the same technical documentation, classification, Basic UDI-DI, MDA or MDN code for Class IIa and EMDN code for higher-class devices. As well, the preclinical, clinical and risk analysis report shall be common to all devices covered by a single Product Information Questionnaire.
5. 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 the SGS website).
6. Please provide the Product Information Questionnaire(s) with the Medical Device Questionnaire and List of Relevant Subcontractors and Suppliers form (available on our website) to your local SGS office.
7. Please attach a list of all devices covered by this PIQ, including Basic UDI-DI and UDI-DI.
8. Please attach additional information concerning this device/device category (flyer, commercial brochure).
9. Please be aware that this document is intended to collect sufficient data to compile a contract proposal for certification. Questions related to, for example, 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: http://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=notification.pdf&dir_id=13&ntf_id=275721
10. 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 provided information is complete and sufficient to understand the device/device category and the quality management system processes to design, develop, manufacture and/or distribute the device.
2. SGS Delivering Office needs to make sure the completed and signed, by the legal manufacturer, PDF document and completed Word document are available.
3. Be sure that all relevant codes (MDA/MDN/MDS/MDT, complex code, EMDN code, clinical code), number of products and provided information are consistent in all submitted documents (MD Questionnaire, PIQ, TDM…)

Part A – to be completed by the client

SECTION 1: CONTACT INFORMATION	
Company name (legal manufacturer):	
European Single Registration Number (ESR/SRN):	

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. Preferably, this includes a drawing, picture or photo):		
Basic UDI-DI and associated UDI-DI:		
Intended use and 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 Annex XVI device, according to the Regulation (EU) 2017/745:		
Is this device currently certified under MDD 93/42/EEC by SGS? If yes, please provide the certificate number:		
Is this device currently certified under MDD 93/42/EEC by another Notified Body? If yes, please provide details and attach the relevant certificate:		
Classification (only one selection possible):	I sterile I reusable	I measuring I sterility + measuring
	IIa non-implantable IIb implantable IIb others	IIa implantable IIb active devices intended to administer and/or remove medicinal products, body liquids or other substances to or from the body (Rule 12)
	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:			
Choice of conformity assessment route, according to MDR 2017/745 (please choose only one conformity route for your certification): Annex IX (quality management system and 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 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). 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). 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).		
European MD[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:
Does your device incorporate tissue or cells of animal origin or derivatives (e.g. gelatin, collagen)? Yes No Please detail, including the number of unique types of animal tissue components:			
Does your device incorporate tissue or cells of human origin or derivatives (e.g. gelatin, collagen)? Yes No Please detail:			
Do you use e-labeling (implementing Regulation EU 2021/2226) for your device? Yes No Please detail:			
Does your device incorporate or consist of nanomaterial? Yes No Please detail:			
Does your device incorporate medicinal products or pharmaceuticals? Yes No Please detail, including the number of unique types of medicinal products or pharmaceutical ingredients:			
Does your device incorporate or consist of software? Yes No Please detail:			
Does your device incorporate or consist of artificial intelligence? Yes No Please detail:			

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

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

Is your device manufactured in a controlled environment or cleanroom? Yes No
Please detail:

Does your device claim innovative characteristics that are considered state-of-the-art? Yes No
Please detail:

Has there been any clinical investigation regarding your device? Yes No
Please detail:

Is your device sterile? Yes No

Sterilization is done 'in-house': Yes No Not applicable

Sterilization method: Aseptic process Ethylene oxide Gamma irradiation
Moist heat (steam) Hydrogen peroxide Electron beam

Any other method(s) – please provide details of the sterilization method(s) used:

For sterile devices – is sterilization outsourced, please detail the number of sterilization subcontractors used per sterilization method? If sterilization is performed in-house, please detail the number of sterilizers:

For non-sterile devices – is sterilization performed by the end user? If yes, please provide details of sterilization method(s) used:

Sterilization for reusable devices –
Please detail the number of devices and the recommended sterilization method:

Is the device electro-medical?

Yes No

If yes, do you use harmonized standards, such as the EN 60101 family, for your device to show presumption of conformity? Detail:

Is testing carried out in-house?

Is testing carried out at unaccredited third-party test house (no accreditation to ISO 17025)?

Is testing carried out at an accredited third-party test house?

Are alternative methods for testing used?

CLINICAL EVALUATION CONSULTATION PROCEDURE (CECP)

Is the device Class III implantable, or Class IIb (Rule 12) for administration and/or removal of medicinal products (ARMP)?

Yes No

If yes, can it be exempt from CECP following MDR Article 54, 2(b) and MDCG 2019-03 Rev1? Yes No

If yes, please provide the following documents to support your justification:

- A statement that the device in question has been marketed for the same intended purpose under the relevant directive
- A copy of the last issued certificate(s) with the certificate history
- A description of the modifications introduced to comply with the MDR. This includes changes, such as labeling, packaging, implant card, etc., as well as design changes to the device to be marketed under the MDR, compared with the previous device certified under the MDD)

SECTION 3: TECHNICAL DOCUMENTATION (INCLUDING CLINICAL EVALUATION)

Name or number of the technical documentation:

Number and list the device variants covered by this technical documentation:

Number and list of device accessories covered by this 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 preapplication, is added: Yes No

If No, confirm such draft EU declaration of conformity will be added to the application (as required by MDR 2017/745):

Yes No

TECHNICAL DOCUMENTATION

Structure: The technical documentation follows Annex II and III:

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 an application is at the Notified Body's discretion):

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

Process flowchart attached: Yes No

Are all concerned devices covered by the same risk management report? Yes No

Are all concerned devices covered by the same preclinical report? Yes No

Are all concerned devices covered by the same clinical evaluation report? Yes No

SECTION 5: ATTACHMENTS	
The next documents are attached (add more lines if needed):	
Document title:	Content:
1.	List of devices covered by this PIQ with Basic UDI-DI and UDI-DI
2.	
3.	
4.	

SECTION 6: DECLARATIONS AND CONFIRMATION (according to Article 53 of MDR 2017/745)	
Undersigned declares that:	
• No application is or will be lodged in parallel with another Notified Body for the same device-related conformity assessment: Please detail the Notified Body if the answer is Not confirmed:	Confirmed Not confirmed
• No application with another Notified Body is withdrawn (by you as the applicant) before the Notified Body's decision regarding the conformity assessment: Please detail the Notified Body if the answer is Not confirmed 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: Please detail the Notified Body if the answer is Not confirmed who refused the application:	Confirmed Not confirmed

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

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:

Part B – application review technical

TO BE COMPLETED BY SGS (APPROVAL BY NB 1639)

<table>
<tr><td colspan="2">Notified Body SGS Belgium accepts the device described above as:
• A medical device (for human use), or
• An accessory for medical devices, or
• A product listed in MDR 2017/745 Annex XVI,
for which MDR is applicable (based on the preliminary information above):
Justification in case No is selected:</td><td colspan="2">Yes No</td></tr>
<tr><td colspan="2">Notified Body SGS Belgium accepts the classification of the device described above
(based on the preliminary information above):
Justification in case No is selected:</td><td colspan="2">Yes No</td></tr>
<tr><td colspan="2">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 No is selected:</td><td colspan="2">Yes No</td></tr>
<tr><td colspan="2">Notified Body SGS Belgium confirms that:
• The applied for conformity assessment route (as described above)
• The device to be certified (as described above)
are covered by Notification of the Notified Body SGS Belgium, No. 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 No is selected:</td><td colspan="2">Yes No</td></tr>
<tr><td colspan="2">Is the device described above acceptable for certification assessment by the Notified Body SGS Belgium?</td><td colspan="2">Yes No</td></tr>
<tr><td colspan="2">Justification of decision (in case of a refusal, the motivation needs to be clearly documented):</td><td colspan="2"></td></tr>
<tr><td>Estimation of the time needed for initial and renewal review of the TD by a PA, according to LPMDREG1022:</td><td>Default time:</td><td></td><td></td></tr>
<tr><td>If a non-default assessment time is specified, this needs to be justified (e.g. innovative device):</td><td>Specific:</td><td>Justification:</td><td>Estimated time:</td></tr>
<tr><td colspan="2">Clinical codes (see LPMDREG7007, Annex II):</td><td colspan="2"></td></tr>
<tr><td colspan="2">Which specialization is required (e.g. electro-medical engineer, radiation physicist)?</td><td colspan="2"></td></tr>
<tr><td colspan="2">Estimation of time needed for technical project management:</td><td>Estimated time:</td><td>Justification (optional):</td></tr>
<tr><td colspan="2">Estimation of time needed by the technical expert:</td><td>Estimated time:</td><td>Justification (optional):</td></tr>
<tr><td colspan="2">Approved by CWS approver:</td><td colspan="2">Date:</td></tr>
</table>

PART C – preapplication review clinical

TO BE COMPLETED BY SGS (APPROVAL BY IHC)

Estimation of the 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…):	Note: This time is only applicable when a clinical oversight is scheduled following the technical documentation assessment plan. This time estimation does not indicate whether clinical oversight is needed for the device.		
Is an external clinical expert necessary (based on the preliminary information above)?	To be decided after the initial TDA Yes No		
Which field of expertise is required (e.g. cardiologist, neurologist, dermatologist)?			
Estimation of the time needed by the clinical expert:	Estimated time:	Justification (optional):	
CLINICAL EVALUATION CONSULTATION PROCEDURE (CECP) 1. Does SGS consider the device qualified for CECP (i.e. Class III implantable or IIb ARMP devices)? Yes No 2. Based on the justification provided by the manufacturer, can the device be exempt from CECP? Yes No			
Approved by IHC:	Date:		