System and procedure pack product information questionnaire

*** For products where CE certification by SGS Belgium NV (Notified Body 1639), 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 must be completed by the client/applicant, while Part B is 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 must be completed for each system or procedure pack to be certified under the Medical Devices Regulation (EU) 2017/745.
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 our website).
6. Please provide the System and Procedure Pack Product Information Questionnaire(s) alongside the Medical Device Questionnaire and List of Relevant Subcontractors and Suppliers (available on our website) to your local SGS Delivering Office.
7. Please attach a list of all devices covered by this System and Procedure Pack Product Information Questionnaire (SPIQ), including Basic UDI-DI and UDI-DI.
8. Please attach additional information concerning this device/device category (flyer, commercial brochure, etc.).
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 SGS NB 1639 is able or allowed to certify such devices. The notification scope of SGS Belgium NV (NB 1639) 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. SGS NB 1639 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 ensure that the provided 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. The SGS Delivering Office must make sure the completed and signed, by the legal manufacturer, PDF document and the completed Word document are available.
3. Ensure that all relevant codes (MDS/MDT, complex code, clinical code), number of products and provided information are consistent in all your submitted documents (MD Questionnaire, System and Procedure Pack Product Information Questionnaire, TDM, etc.).

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. This should include a drawing, picture or photography):*	Confirmation that the client has:	
		Verified the mutual compatibility of the devices according to the manufacturers' instructions: Yes No	Carried out their activities (including sterilization) according to those instructions: Yes No

Details of the system or procedure pack components *Provide a complete list of each system or procedure pack component, including quantities, and the following details in full:*		
Whether the component is a medical device, a product that is not a medical device, or an in vitro diagnostic medical device:	Whether the component is CE-certified and provide details (for medical devices or in vitro medical devices):	Whether the component is compliant with the respective legislation that applies to it (for a product that is not a medical device):

Intended use and clinical claims *(including, where applicable, clinical indications and intended patient population):*	Basic UDI-DI:

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 a relevant certificate:

Coding of the device according to the European Regulation 2017/2185 Codes (for the device to be certified)[1] *Select the appropriate codes from the drop-down list. These codes must be selected by the applicant:*	
MDS codes *(Each device can bear several MDS codes. If SGS NB 1639 is assessing a system or procedure pack under Article 22, we will be reviewing the sterility aspects only. Therefore, the only relevant MDS codes are MDS1005 and/or MDS1011):*	MDT codes *(If SGS NB 1639 is assessing a system or procedure pack under Article 22, we will be reviewing the sterility aspects only. Therefore, the only relevant MDT code is MDT2011):*

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)

This device is sterile: Yes No Sterilization is done 'in-house': Yes No Not applicable	Sterilization agents Aseptic process: *(If other sterilization agents were used for the aseptic process to sterilize the packaging/bulk materials, please specify:* • The sterilization agents (i.e. steam, irradiation, dry heat, EO) • The types of materials sterilized	Ethylene oxide Irradiation – gamma/ electron beam/X-ray Moist heat (steam) Hydrogen peroxide Any other agents – please specify:

[1] https://eur-lex.europa.eu/eli/reg_impl/2017/2185/oj

If the sterilization is outsourced, please detail the number of sterilization subcontractors used per sterilization agent:		
If the sterilization is performed in-house or outsourced, please detail below for each sterilizing agent: • Number of sterilizers: • Numbers of cycles per sterilizer:	Does any of the device/technical documentation share any sterilization validation? If yes, please provide details:	
Shelf-life (accelerated, real-time and transit) – please provide details:	Does any of the device/technical documentation share any shelf-life validation?	If more than one shelf-life study was performed. Please provide the number of reports and details:

SECTION 3: TECHNICAL DOCUMENTATION (INCLUDING CLINICAL EVALUATION)

The name or number of the Technical Documentation:	Number and list of device variants covered by this Technical Documentation *(Please attach a document including the differences between the variants):*	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 (according to MDR 2017/745 Article 19 and Annex IV) for the device model covered by this pre-application is added: Yes No	If 'no', confirm that 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	

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 SGS NB 1639):*
Please attach a process flow chart, including the identification of the different sites involved and the outsourced processes.	Process flow chart attached: 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 SPIQ with Basic UDI-DI and UDI-DI:
2.	
3.	

SECTION 6: DECLARATIONS AND CONFIRMATION (ACCORDING TO ARTICLE 53 OF MDR 2017/745)

The undersigned declares that:		
No application is or will be lodged in parallel with another Notified Body for the same device-related conformity assessment procedure: Confirmed Not confirmed *Please detail the Notified Body if the answer is '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: Confirmed Not confirmed *Please detail the Notified Body if the answer is 'Not confirmed' whose application is withdrawn:*	No previous application with another Notified Body is refused (by that Notified Body) for the same conformity assessment: Confirmed Not confirmed *Please detail the Notified Body if the answer is 'Not confirmed' who refused the application:*

Confirmation (by the legal manufacturer) *(please send the completed document in Word and the signed document in PDF):* The information in this application 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 a change in the provided service and price.	Name: Date: Position: Signature:

PART B: – pre-application review to be completed by SGS (approval by SGS NB 1639)

SGS Belgium NV (NB 1639) accepts the device described above as: • A medical device (for human use), • An accessory for medical devices, or • A product listed in MDR 2017/745 Annex XVI for which MDR applies (based on the preliminary information above):	Yes No Justification in case 'No' is selected:
SGS Belgium NV (NB 1639) confirms the applied for conformity assessment route applies to the device described above: *(based on the preliminary information above)*	Yes No Justification in case 'No' is selected:
SGS Belgium NV (NB 1639) 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 SGS Belgium NV (NB 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):*	Yes No Justification in case 'No' is selected:

Is the device as described above acceptable for certification assessment by the SGS Belgium NV (NB 1639)? 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 TD by a PA according to LPMDREG1022. *If a non-default assessment time is specified, this needs to be justified (e.g. innovative device).*	Default time:	Specific:	Justification: Estimated time:
Approved by Technical Coordinator:			Date: