

Product information questionnaire

**FOR PRODUCTS WHERE CE CERTIFICATION BY SGS BELGIUM NV
(NOTIFIED BODY 1639) ACCORDING TO REGULATION (EU)
2017/746 IS SOUGHT.**



This document should not be completed for devices that do not require a CE certificate from a Notified Body (e.g. devices under self-declaration).

Completion Guidance Notes

1. PART A of this questionnaire is to be completed by the client/applicant, whereas PART B and C are to be completed by SGS.
2. For SGS to be able 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 of the questions, please type "don't know" and one of our technical team will contact you to discuss any uncertainties.
4. One form must be completed, for each device to be certified under In Vitro Diagnostic Medical Devices Regulation (EU) 2017/746. This form may only cover multiple devices in the case where they:
 - are covered by the same set of technical documentation, including one risk management report and one performance evaluation report, and
 - share the same Basic UDI-DI, and
 - belong to the same risk class, and
 - share the same IVR code for Class B devices or same combination of EMDN code with IVP code for Class C devices.

For devices which belong to the same generic device group (Class C) or category of device (Class B), but which do not fulfill the criteria above, we request you to provide us with a separate Product Information Questionnaire (PIQ) per device.

5. If you are an existing client applying for certification of additional products, 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 Product Information Questionnaire(s) together with 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 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. SGS Belgium NV (NB 1639) is designated to certify a wide range of devices, including Class A Sterile, Class B and Class C (excluding the highest-risk Class D and companion diagnostic devices). The scope of SGS Belgium NV (NB 1639) designation can be found on the official Nando database: <https://webgate.ec.europa.eu/single-market-compliance-space/notified-bodies>
10. SGS Belgium NV (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 the provided information is complete and sufficient to understand the device/device category and the Quality Management System (QMS) 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, as well as the completed Word document, is available.
3. Be sure that all relevant codes (IVR/IVS/IVT/IVP/IVD, complex code, EMDN code, clinical code), number of products and provided information are consistent in between all submitted documents (Medical Device Questionnaire, Product Information Questionnaire, TDM, ...)

PART A - TO BE COMPLETED BY THE CLIENT**SECTION 1: CONTACT INFORMATION**

Company name (Legal Manufacturer):

European Single Registration Number (SRN):

SECTION 2: COMPANY INFORMATION

The Notified Body is required to gather the information below to fulfill its impartiality obligations under European legislations.

Please provide other legal identities or trade names under which the Legal manufacturer has operated in the last 3 years:

If the manufacturer is part of a group of companies, please provide the company names for all members of the group:

Please provide names of any companies acquired by or merged with the manufacturer in the last 3 years:

SECTION 3: PRODUCT DESCRIPTIONDevice 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 Performance Claims:
(including, where applicable, clinical indications and intended patient population and intended users)

Qualification of this device according to the definitions in Regulation (EU) 2017/746:

In vitro diagnostic medical device for human use

Accessory of an in vitro diagnostic medical device for human use

Please provide a justification as to why this device is considered an in vitro diagnostic medical device or an accessory according to Regulation (EU) 2017/746:

Is this device currently certified under UK MDR 2002 by SGS? If yes, please provide the certificate number:

Is this device currently certified under **IVDD 98/79/EC** by another Notified Body? If yes, please provide details and attach the relevant certificate:Specific device characteristics:
(please select all relevant options which apply to the device)

- Device for self-testing
- Device for near-patient testing
- Companion diagnostic device
- Calibrator or control material included with the device
- Standalone control material
- Standalone IVD instrument
- Instrument included as part of assay device
- Specimen receptacle
- Reagent or accessory with no critical characteristics (as per IVDR Annex VIII paragraph 2.5)
- Device is an IVD kit (as per IVDR Article 2 (11))
- Controls with no assigned values

IVDR Classification: (only one selection possible)	Class A Sterile Class B Class C Class D (outside of SGS NB 1639 designation scope)		
Justification of classification (+ applied rule) according to Annex VIII of IVDR 2017/746:			
Choice of conformity assessment route according to IVDR 2017/746 (please choose only one conformity route for your certification): Annex IX (Quality Management System & Technical Documentation) Annex XI (Production Conformity Assessment) – only Class A sterile Article 16 for distributor or importer only			
Coding of the device according to the European Regulation 2017/2185 Codes (for the device to be certified) ¹ : Select applicable appropriate codes from the drop-down list. These codes are mandatory to be selected by the applicant.	<p>IVR Codes <i>(based on the intended purpose and design of the IVD: higher codes should be applied since only one² IVR code can be assigned to the particular device)</i></p> <p>IVS Codes <i>(indicate the specific features of devices: each device can bear several IVS codes (under the general rule – all applicable codes) or could have no such codes assigned at all. To be assigned after an IVR code has been assigned)</i></p> <p>IVT Codes <i>(indicate the technological processes utilized during the manufacturing of the device: each device should have at least one IVT code assigned after an IVR code has been assigned)</i></p> <p>IVP Codes <i>(assign the codes that describe the main examination procedures: each device should have at least one³ IVP code assigned after an IVR code has been assigned)</i></p> <p>IVD Codes <i>(assign the codes that describe the main laboratory and clinical disciplines: each device can bear several IVD codes (under the general rule – all applicable codes) or could have no such codes assigned at all after an IVR code has been assigned)</i></p>		
European Medical Device Nomenclature ⁴ full code:	Not yet determined	Code:	Description:

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

²MDCG 2021-14: Cases may exist in which more than one IVR code is assigned.

³MDCG 2021-14: Exceptional cases may exist that no IVP code is assigned (e.g. controls or specimen receptacles).

⁴<https://webgate.ec.europa.eu/dyna2/emdn/>

Other internationally recognized medical device nomenclature code and related description (e.g. Global Medical Device Nomenclature (GMDN) code and related description):	Not Applicable	Code:	Description:
	Other nomenclature is used:		
Does the device incorporate materials of biological origin?	Yes No	Details:	
Does the device incorporate tissue or cells of human origin or derivatives (e.g. red blood cells as control for blood grouping)?	Yes No	Details:	
Is the device a stand-alone software?	Yes No	Details:	
Does the device incorporate software?	Yes No	Details:	
Does the device incorporate Artificial Intelligence technologies?	Yes No	Details:	
Is the device manufactured in a controlled environment or clean room? Please provide details. Indicate whether these activities are performed in-house or outsourced.	Yes No	Details:	
Does your device claim innovative characteristics compared with the state-of-the-art?	Yes No	Details:	
Have any performance studies been conducted for your device?	Yes No	Details:	
Is the device an IVD kit as defined in IVDR Article 2 (11)? If yes, please provide details of kit components and their regulatory status.	Yes No	Details:	

Does the device incorporate electrical, electronic and/or electro-mechanical components?	Yes	No
If yes, Do you apply standards, such as the IEC 61010 series to demonstrate the conformity of your device with applicable requirements?	Yes	No
Is testing carried out in-house?	Yes	No
Is all testing carried out by an ISO 17025-accredited test provider?	Yes	No
Is any alternative, non-standardized method used for testing?	Yes	No
Shelf-life – please provide details on the number and nature (such as accelerated, real time and transit) of shelf-life studies conducted:	Details:	
If multiple devices are included in this Product Information Questionnaire: <ul style="list-style-type: none"> Please indicate whether the shelf-life validation is shared between the devices or is separate hereto. If more than one shelf-life study was performed, please provide details (such as scope) and number of studies and associated shelf-life validation reports.	Applicable	Not Applicable
Article 16 certification: If your organization is applying for certification under Article 16 for distributor or importer only, please note that the sections below dedicated to sterility aspects can be disregarded. Nevertheless, please provide an answer to the following question:		
Article 16 certification only: Do the repackaging activities affect sterility?	Yes	No
Please indicate the sterility aspect of the device:	Not Applicable Non-sterile device Sterile device Non-sterile device intended to be sterilized by the end-user Reusable device requiring cleaning, disinfection, sterilization or refurbishment between uses	
<i>If the device is non-sterile and is not intended to be sterilized by the end user, the sections below regarding sterility aspects can be disregarded.</i>		
The section below only applies to devices placed on the market in a sterile state.		
Is sterilization done 'in-house'?	Yes	No
Sterilization agents: for each sterilizing agent selected, please indicate number of sterilizers and number of cycles per sterilizer, where relevant.		

<p>Aseptic process</p> <p>If other sterilization agents were used for the aseptic process to sterilize the packaging / bulk materials, please specify:</p> <ul style="list-style-type: none"> • Sterilization agents (i.e. Steam, Irradiation, Dry heat, EO) • Type of materials sterilized 	<p>Details:</p> <p>Applicable Not Applicable</p> <p>Details:</p>
<p>Ethylene Oxide</p>	<p>Details:</p>
<p>Irradiation – Gamma/ Electron Beam/ X-ray</p>	<p>Details:</p>
<p>Moist heat (steam)</p>	<p>Details:</p>
<p>Hydrogen peroxide</p>	<p>Details</p>
<p>Any other agents – Please specify</p>	<p>Details:</p>
<p>If sterilization is outsourced, please detail the number of sterilization subcontractors used per sterilization agent:</p>	<p>Details:</p>
<p>Sterilization validation</p> <p>If multiple devices are included in this Product Information Questionnaire:</p> <ul style="list-style-type: none"> • Please indicate whether the sterilization validation is shared between the devices or is separate hereto. <p>If more than one sterilization validation was performed, please provide details (such as scope) and number of sterilization validation reports.</p>	<p>Applicable Not Applicable</p> <p>Details:</p>
<p>The section below only applies to devices that are intended to be sterilized by the end-user.</p>	
<p>Please indicate the sterilization agent(s) to be used:</p> <ul style="list-style-type: none"> • Ethylene oxide • Irradiation • Moist heat (steam) • Others 	<p>Details:</p>

<p>Cleaning validation</p> <p>If multiple devices are included in this Product Information Questionnaire:</p> <ul style="list-style-type: none"> Please indicate whether the cleaning validation is shared between the devices or is separate hereto. <p>If more than one cleaning validation was performed, please provide details (such as scope) and the number of cleaning validation reports.</p>	<p>Applicable Not Applicable</p> <p>Details:</p>
<p align="center">The section below only applies to reusable devices requiring cleaning, disinfection, sterilization or refurbishment between uses.</p>	
<p>Sterilization for reusable devices</p> <p>Please detail the number of allowable reuses, the recommended cleaning and sterilization agent.</p>	<p>Applicable Not Applicable</p> <p>Details:</p>
<p>Reusability validation including product performance</p> <p>If multiple devices are included in this Product Information Questionnaire:</p> <ul style="list-style-type: none"> Please indicate whether the reusability validation is shared between the devices or is separate hereto. <p>If more than one reusability validation was performed, please provide details (such as scope) and the number of reusability validation reports.</p>	<p>Applicable Not Applicable</p> <p>Details:</p>
<p>Cleaning validation</p> <p>If multiple devices are included in this Product Information Questionnaire:</p> <ul style="list-style-type: none"> Please indicate whether the cleaning validation is shared between the devices or is separate hereto. <p>If more than one cleaning validation was performed, please provide details (such as scope) and the number of cleaning validation reports.</p>	<p>Applicable Not Applicable</p> <p>Details:</p>

<p>SECTION 4: TECHNICAL DOCUMENTATION (INCLUDING PERFORMANCE EVALUATION)</p> <p><i>This section is not applicable to Article 16 certification.</i></p>	
<p>Name or number of the Technical Documentation:</p>	
<p>Number and list of device variants covered by this Technical Documentation: (please attach a document that contains and explains differences between variants)</p>	
<p>Number and list of device accessories covered by this Technical Documentation:</p>	
<p>Confirmation that the full Technical Documentation is in English:</p>	<p>Yes No</p>
<p>A draft of an EU declaration of conformity (in accordance with IVDR 2017/746 Article 17 and Annex IV) for the device model covered by this pre-application, is added:</p>	<p>Yes No</p>
<p>If 'no', please confirm that such draft EU declaration of conformity will be added to the application (as required by IVDR 2017/746):</p>	<p>Yes No</p>

Technical Documentation:	Structure: The Technical Documentation follows Annex II & III:	Yes	No
Performance evaluation and performance studies:	Performed according to requirements of Annex XIII Part A of IVDR:	Yes	No
	Please detail: Documentation completed and available for submission	Yes	No

SECTION 5: QUALITY MANAGEMENT SYSTEM RELEVANT TO THE DEVICE

Is the Quality Management System documentation entirely in English? If not, and there is no validated translation available, please specify which record(s) are only accessible in another language (in such case, the acceptance of an application is at the discretion of the Notified Body):	Yes No
Please attach a process flow chart, including the identification of the different sites involved and indicate any outsourced processes.	
Process flow chart attached:	Yes No
Are multiple devices covered by this Product Information Questionnaire?	Yes No
Are all concerned devices covered by a single risk management report?	Yes No
Are all concerned devices covered by the same set of verification and validation documentation?	Yes No
Are all concerned devices covered by the same set of performance evaluation documentation?	Yes No

SECTION 6: 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	
5	

SECTION 7: DECLARATIONS AND CONFIRMATION (ACCORDING TO ARTICLE 49 OF IVDR 2017/746)

I, the undersigned, declare that:

<ul style="list-style-type: none">No application has been lodged with another Notified Body for the same conformity assessment procedure of the device(s) described in this document. <p><i>(If “not confirmed”, please provide details)</i></p>	Confirmed	Not Confirmed
<ul style="list-style-type: none">No application for conformity assessment of the same device(s) has previously been lodged with and withdrawn from another Notified Body prior to the decision of that Notified Body. <p><i>(If “not confirmed”, please provide details regarding the previous application)</i></p>	Confirmed	Not Confirmed
<ul style="list-style-type: none">No application for conformity assessment of the same device(s) has been previously refused by another Notified Body. <p><i>(If “not confirmed”, please provide details regarding the refusal by another Notified Body)</i></p>	Confirmed	Not Confirmed
<ul style="list-style-type: none">I understand that I am not permitted to lodge an application for conformity assessment of the device(s) described in this document with another Notified Body in parallel with this application.	Confirmed	Not Confirmed

Confirmation (by the legal manufacturer): (please send the completed document in Word and signed document in 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 the provided service or price.

Signature

Name and date

Position

PART B: PRE-APPLICATION REVIEW TECHNICAL

SGS Belgium NV (NB 1639) accepts the device described above as:		Yes	No			
<ul style="list-style-type: none"> In vitro diagnostic medical device (for human use) Accessory for an in vitro diagnostic medical device (for human use) Device for self-testing Device for near-patient testing 						
For which IVDR is applicable (based on the preliminary information above):						
Justification in case 'No' is selected:						
SGS Belgium NV (NB 1639) accepts the classification of the device described above (based on the preliminary information above):		Yes	No			
Justification in case 'No' is selected:						
SGS Belgium NV (NB 1639) confirms the applied conformity assessment route is applicable 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:		Yes	No			
<ul style="list-style-type: none"> the applied conformity assessment route (as described above) the device to be certified (as described above) 						
<p>are covered by Notification of the SGS Belgium NV (NB 1639), as referenced in LPP MDR.IVDR.00 (scope publicized in the Nando database under control of the European Commission)</p> <p>(based on the preliminary information from the manufacturer):</p>						
Justification in case 'No' is selected:						
Is the device 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)						
<p>Estimation of the time needed for initial and recertification review of the TD by a PA according to LPMDR.IVDR1022.</p> <p>If a non-default assessment time is specified, this needs to be justified (e.g. innovative device).</p>	<p>Default time:</p> <table border="1"> <tr> <td>Specific:</td> <td>Justification:</td> <td>Estimated time:</td> </tr> </table>			Specific:	Justification:	Estimated time:
Specific:	Justification:	Estimated time:				
Clinical codes (see LPMDR.IVDR7007):						
Which specialization is required? (e.g., electro-medical engineer, radiation physicist, biosafety, functional safety, (genetic, microbiological, chemical engineer), sterilization, software specialist)						
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 Technical coordinator:	Date:	

PART C: PRE-APPLICATION REVIEW - CLINICAL TO BE COMPLETED BY SGS (APPROVAL BY IHC)		
<p>Estimation of the time needed for performance evaluation clinical oversight:</p> <p>(as per LPMDR.IVDR1022)</p> <p>If a non-default assessment time is specified, please provide justification: e.g. innovative device, complex device, multiple models, etc.</p>	<p>Note: this time is applicable only when a performance evaluation clinical oversight is scheduled following technical documentation assessment plan. This time estimation does not indicate whether performance evaluation clinical oversight is needed for this device.</p>	
<p>Is an external clinical expert necessary?</p> <p><i>(based on preliminary information above)</i></p>	<p>To be decided after initial TDA</p> <p>Yes</p> <p>No</p>	
Which field of expertise is required? (e.g., geneticist)		
Estimation of time needed by the clinical expert (days):		
Approved by IHC:	Date:	