Medical devices notification of changes, regulatory action, consultancy or services rendered

***** FOR USE UNDER BOTH MDD AND MDR *****

You are required to inform SGS beforehand of any changes or regulatory actions that may affect the:

- Certified (approved) device, where such changes could impact conformity with essential requirements (for MDD certification) of the device
- General safety and performance requirements (for MDR certification) of the device or conditions prescribed for use of the device
- Validity of your current certification
- Scope of an audit
- Possible unannounced audit sites (e.g. legal manufacturer's site, site of any other company location, site of relevant supplier and/or subcontractor, or other)
- Periods of availability for the different possible unannounced audit sites

Where you, as the legal manufacturer, plan to introduce any of the above changes, you are required to inform, well beforehand, the Notified Body SGS Belgium thereof.

The Notified Body SGS Belgium shall assess the planned changes and decide whether they require a new conformity assessment or could be addressed using a supplement to the EC design-examination certificate (for MDD certification), or EU technical documentation assessment certificate (for MDR certification). For the latter, the Notified Body shall assess the changes, notify the manufacturer of its decision and, where the changes are approved, provide a supplement to the certificate.

It is also important to inform SGS of consultancy and services rendered concerning medical devices to avoid any (suspicion or potential) conflict of interest (e.g. if consultancy is rendered from a consultant who is also a medical device auditor for SGS, or if testing services are rendered from a company within SGS Belgium Group). This form should not be used for vigilance notifications.

This notification is to be made using this form as soon as the information related to the change in your quality management system is known.

After May 26, 2021, the change must be considered with regards to MDCG 2020-3, to determine whether it is significant/not significant and, if considered not significant, justification must be provided within this form.

This form must be used to inform SGS of:

- Any significant changes or extensions that may affect current certification, including:
  - Company name, locations and number of employees
  - Addition/removal of products from the scope
  - Changes to the certified (approved) device
  - Relevant MDR/crucial MDD subcontractors
  - Relevant MDR/crucial MDD suppliers
  - Any changes to sterilization processes
  - SGS-approved quality management systems
- Changes to data held by SGS:
  - Contact names
  - Periods of unavailability for unannounced audits
- New/changed consultancy and services rendered concerning medical devices
- Any regulatory actions taken by you or any Regulatory Authority (e.g. EU Vigilance, product recall, FDA warning letter, new clinical investigation, etc.)

Note:

- Requests for additional types of certification, other than either of the above, will require the completion of a medical device questionnaire (available on the SGS website: https://www.sgs.com/en/our-services/health-and-nutrition/health-science/eu-medical-devices-regulations-information-center)
- Requests for additional device ranges to be certified will require the completion of a product medical device questionnaire (available on the SGS website: https://www.sgs.com/en/our-services/health-and-nutrition/health-science/eu-medical-devices-regulations-information-center)

After review of any notified change or regulatory action, SGS will:

- Verify the change at the next scheduled audit, at no extra cost
- Update its database
- Change the wording on the certificate and make an administration charge
- Inform you that extra time is required at the next audit
- Undertake an additional audit or assessment, for which you will be sent a costed proposal
- Amend your future audit schedule to reflect the change
- Conduct any other action described below, as deemed needed by the Notified Body SGS Belgium

You, as the legal manufacturer, sign for the accuracy and completeness of this change notification, as well as the accuracy of all 'client data'. Notified Body SGS Belgium may use this data, without a new proposal and application form or confirmation, for regulatory (including a new revision of a certificate) and administrative purposes.

The approval by Notified Body SGS Belgium of this MD Product Change Notification Form does not grant permission to implement the notified change(s). The decision related to the notified changes is described in the section Review of Notification by Notified Body SGS Belgium.

Devices cannot be placed on the market until Notified Body SGS Belgium has notified you, in writing, of this decision. See the end of this document, the section Conclusion.

If, in section 4 below, a "proposal for costs associated with Change to Scope" is requested by the Notified/Certification Body, to assess the notified change, then the notified change is only to be implemented after the Change to Scope assessment is contractually agreed, performed, finished (major nonconformities closed), finally approved and communicated, in writing, by the Notified/Certification Body.

The certified device(s) placed on the market, after having implemented the changes related to these devices before formal approval in writing by the Notified Body, are deemed not covered by the issued CE certificate of the Notified Body and, thus, are not legally placed on the market.

Please complete and return this form, in an editable, electronic format, to the SGS Office that manages your medical device certification contract.

Client name:	Date:
Client contact name:	
Client SRN (mandatory under MDR):	
Contact tel:	Email:
Person responsible for regulatory compliance (if different):	
SGS contract number (if known):	
If reporting a change to a device, the device name and Basic UDI-DI (mandatory under MDR):	
Current SGS certificate number(s): ISO 13485 certificate(s): CE certificate(s):	

1. WE ARE NOTIFYING YOU OF THE CHANGES DETAILED BELOW Change to (changes can include additions and deletions)	
Please check all relevant categories of change and give details.	
The certified name and address, other site addresses, activities/scopes/ownership:	☐
Name and email of primary or secondary contact person:	☐
Number of employees covered by the scope of certification:	☐
Relevant MDR or crucial MDD subcontractors (give name, address and product/service supplied for new subcontractors):	☐
Relevant MDR or crucial MDD suppliers (give name, address and product/service supplied for new suppliers):	☐
The structure of the quality management system or links with related companies:	☐
Major quality system processes or activities:	☐
Major production, testing or inspection processes:	☐
Sites where unannounced audits might take place (where final assembly/acceptance testing is undertaken):	☐
Periods of unavailability (i.e. when an unannounced audit cannot take place) within the next 12 months:	☐
Medical device product range (i.e. change to generic types manufactured or to classifications):	☐
New person responsible for regulatory compliance:	☐
New device:	☐
Change to an existing device (e.g. design, intended use, IFU, claims, materials, production technology, medicinal products or animal tissues, performance or conformance with standards):	☐
Other (please give details):	☐

Details of change *(attach additional documents if required).*
Brief description of the modifications compared to the previous situation:
Reason and origin for the changes/modifications:
Which certificates are impacted by this change? (Provide certificate numbers):
Is there any change to the intended use of the device? (If yes, provide the new intended use and indicate the change with the current intended use):
Has any validation or risk analysis been updated? (If yes, provide more information about which validation is updated or which part of the risk analysis is updated and why this was done):
Please provide details of any technical files to be changed/added:
In the case of design/device changes, a statement on the relevance to the compliance with General Safety and Performance Requirements or Essential Requirements:
If any activities are moving to a new site, please advise of any equipment to be validated and change to employee numbers:
Any further details:
Change date effective from (date must be in the future):

2. WE ARE NOTIFYING YOU OF REGULATORY ACTIONS AND APPROVALS DETAILED BELOW	
Please check relevant boxes and give further information below.	
Regulatory approvals gained or stopped (e.g. US, Brazil, Japan, Australia, Canada):	☐
Regulatory actions by any Regulatory Authority that have required you to take action, supply information or restrict the sale of your medical devices in any market:	☐
Incident reports (vigilance) that have required you to take remedial actions (please attach vigilance report, including your analysis of the root cause, revised/updated risk analysis and actions taken by you):	☐
New clinical investigation started (ethics committee approval required) or performance evaluation started:	☐
Details of regulatory actions and approvals:	

3. WE ARE NOTIFYING YOU OF CONSULTANCY AND SERVICES RENDERED CONCERNING MEDICAL DEVICES DETAILED BELOW	
Please check relevant boxes and give further information below in the section Details.	
Consultancy services in the field of medical devices:	☐
Training activities in the field of medical devices:	☐
Internal audits:	☐
Consultancy services, as regards EU requirements for the design, construction, marketing or maintenance of the products under assessment:	☐
Services related to preclinical studies, clinical evaluation and clinical investigations:	☐
Laboratory testing services (e.g. testing for electro-medical devices):	☐
Clinical research:	☐
DETAILS OF CONSULTANCY AND OTHER SERVICES	
Please provide the name of the organization/person(s) that delivered services in the field of medical devices, for any box that has been checked:	

4. REVIEW OF NOTIFICATION BY SGS NOTIFIED/CERTIFICATION BODY (TO BE COMPLETED BY SGS)

Evaluation after May 26, 2021 (for devices certified under MDD 93/42/EEC).

Next change is considered a Significant Change in Design and/or Intended Use[1], and is not allowed after May 26, 2021, for a device certified under MDD 93/42/EEC. The Notified Body does not allow and approve this change, and the company must have an MDR 2017/745 certificate to implement the notified change. ☐

Not allowed change:

Rationale:

For MDR and, if allowed, MDD 93/42/EEC, the next actions are required (select as appropriate).

1. CHANGE THE DATA IN THE CERTNET DATABASE (NO CHARGE): ☐

The change is approved when this form is signed.
Details to be updated:

2. CERTIFICATE ALTERATION ONLY (ADMINISTRATION CHARGE): ☐

Note: Where devices are being added/removed from the scope of CE 1639 certification, without technical review, the CE certificates will be updated immediately to reflect the devices covered by the CE 1639 scope.
The change is approved when the certificate is reissued.
Details of changes to the certificate:

3. REVIEW AT THE NEXT AUDIT (NO CHARGE): ☐

Note: Implementing the change will be reviewed at the next scheduled audit. Additional time may be required at the next scheduled audit if there are several changes to review.
The change is approved when this form is signed: ☐
The changed is approved after the next audit and no major nonconformities are raised related to this change: ☐
Details of review required:

4. PROPOSAL FOR COSTS ASSOCIATED WITH CHANGE TO SCOPE: ☐

The change is only approved after the proposal is accepted: ☐
The changed is only approved after the additional work is complete, all major nonconformities, as appropriate, are closed and the certificate is reissued: ☐
Details of changes to the certificate:

This notification of changes and regulatory actions has been reviewed by:

Name: (MDO)

Date:

Further remarks (if any):

Clients will be notified via their managing SGS Office of any further actions required following review by the Notified Body.

[1] *See official document: MDCG 2020-3 guidance on significant changes regarding the transitional provision under Article 120 of the MDR, concerning devices covered by certificates according to MDD or AIMDD*