FOR USE UNDER MDD AND MDR

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

It is a requirement to inform SGS NB 1639 beforehand of any changes or regulatory actions that may affect the:

- Certified (approved) device where such changes could affect 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 the use of the device
- Validity of your current certification, or
- Scope of an audit, or
- 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), or
- Periods of availability of the different possible unannounced audit sites

Where you, as the legal manufacturer, plan to introduce any of the changes mentioned above, you must inform, well beforehand[1], SGS NB 1639 thereof, using this form.

Planned changes cannot be implemented, and devices cannot be placed on the market, until formal approval of the change is received in writing by SGS NB 1639. Any certified devices placed on the market with the changes implemented to these devices, prior to 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.

This form, detailing the review and decision of SGS NB 1639, will be returned to you through your local SGS Delivering Office. You will also be notified via your local SGS Delivering Office of any further actions required following review and decision by SGS NB 1639.

SGS NB 1639 shall assess the planned changes or regulatory action, and can decide to:

- 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
- Any other action described below, as deemed necessary by SGS NB 1639

The decision related to the notified changes is described in Section 4 of this form: 'Review of Notification by SGS NB 1639'. If, in Section 4, a 'Proposal for costs associated with Change to Scope' is requested by SGS NB 1639 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 SGS NB 1639.

It is also a requirement to inform SGS NB 1639 of consultancy and services rendered concerning medical devices to avoid any (suspicion or potential) conflict of interest (e.g. if consultancy is rendered by a consultant who is also a medical device auditor for SGS, if testing services are rendered from a company within SGS Belgium Group).

This form should not be used for Vigilance notifications.

[1] *Notification of change is to be made using this form and as soon as the information related to the change in your Quality Management System is known*

ANNEX I: EXAMPLES OF CHANGES THAT SGS NB 1639 MUST BE NOTIFIED OF BEFORE IMPLEMENTATION

This is a non-exhaustive list of substantial examples and, in case of doubt, please contact your local SGS Delivering Office.

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.

	IMPACTED ELEMENT	SUBSTANTIAL CHANGE THAT NEEDS TO BE NOTIFIED
CLINICAL	Change to the intended purpose or indications	All changes to the intended purpose or indications
	PMCF conditions	Any change to the agreed PMCF plan
	Change or addition of an operative technique or manual	All changes to the operative technique or manual
DESIGN	Change to the design specification	All changes impacting design specifications
	Change to the device performance or specification	All changes to the device's performance or specification
	Change of software	Any impact on diagnosis, delivered treatment or software validation
	Product range	Adding or withdrawing devices included in an existing range
	Material	Any replacement of material to the device or device's component
	Mode of operation	Any change
MANUFACTURING PROCESS, EQUIPMENT AND SUPPLIER	Change to the sterilization method	Any change
	Change or new subcontractor/supplier	Any change of supplier
	Manufacturing process and equipment	Any change impacting manufacturing validation
	New cleanrooms or significant change (e.g. expansion) of existing cleanrooms	Any change
LABELING, PACKAGING AND SHELF LIFE	Labeling	Any change in labeling (except minor grammatical errors or aesthetic changes (color change/logo change)
	Change of packaging (all levels)	Any change
	Change in the shelf life	Any change to the device's shelf life
	Agreed conditions or plan for CAPA on remaining open minor CAR	Any extension in time Stop or reduction of agreed study
QMS CHANGES	Contractual data	Company name/address/number of employees/ legal entity
	Management representative	Any change
	The person responsible for regulatory compliance	Any change
	Change in the Quality Management System	Any change
	A significant change in the number of personnel (based on IAF_MD9, Annex D, Table D.1)	Yes
OTHER	Design/manufacturing/labeling/packaging change related to CAPA	Any change
	Data on the certificate	Any information recorded in EUDAMED
	Changes that impact compliance with GSPR (Annex I)	All changes
	Changes that impact the device's safety and performance	All changes
	Changes that impact risk	All changes

NOTE:

- Requests for **additional types of certifications** will require the completion of a full Medical Device Questionnaire (LPMDREG1001)
- Requests for **additional device ranges to be certified** will require the completion of a full Product Information Questionnaire (LPMDREG1010)

You, as the legal manufacturer, sign for the accuracy and completeness of this change notification, as well as the accuracy of all 'client data'.

SGS NB 1639 may use this data, without a new proposal and application form or confirmation, for regulatory purposes (including a new revision of a certificate) and administrative purposes.

Please complete and return this form in an electronic, editable Word format to your local SGS Delivering Office which manages your medical device certification contract.

Client name:	Date:
Client contact name:	
Client SRN (mandatory under MDR):	
Contact telephone number:	Email:
The 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 THE RELEVANT CATEGORIES OF CHANGE AND PROVIDE DETAILS BELOW.	
The certified name and address, other site addresses, activities/scopes/ownership:	
The name and email of the primary or secondary contact person:	
The number of employees covered by the scope of certification:	
Relevant MDR or crucial MDD subcontractors (give names, addresses and products/services supplied for new subcontractors):	
Relevant MDR or crucial MDD suppliers (give names, addresses and products/services 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 classifications):	
The new person responsible for regulatory compliance:	
The 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:	
The reason for and origin of 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 to 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 & Performance Requirements or Essential Requirements:	
If any activities are moving to a new site, please advise of any equipment to be validated and changes to employee numbers:	
Any further details:	

Estimated date of change implementation (date must be in the future and after SGS NB 1639 approval, in any case):

2. WE ARE NOTIFYING YOU OF REGULATORY ACTIONS AND APPROVALS DETAILED BELOW

PLEASE CHECK ALL THE RELEVANT CATEGORIES OF CHANGE AND PROVIDE DETAILS 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):	
The 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 ALL THE RELEVANT CATEGORIES OF CHANGE AND PROVIDE DETAILS BELOW.	
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 NB 1639 (TO BE COMPLETED BY SGS NB 1639)

EVALUATION AFTER MAY 26, 2021 (FOR DEVICES CERTIFIED UNDER MDD 93/42/EEC).	
The next change is considered a significant change in design and/or intended use[2], 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 will need 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 CertIQ 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 the 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 change 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 not approved yet and will require further actions, for which SGS will establish a commercial proposal: The change is **only approved after** the additional work is complete, all major nonconformities, as appropriate, are closed and the certificate is reissued: Details of the proposal required:	

[2] *See the 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*

THIS NOTIFICATION OF CHANGES AND REGULATORY ACTIONS HAS BEEN REVIEWED BY:

Name (MDO): Date: Further remarks (if any):

SGS Headquarters
1 Place des Alpes
P.O. Box 2152
1211 Geneva 1
Switzerland

sgs.com

When you need to be sure