



DEKRA Notice of Change Handling

Customer Guidance





Introduction



This Notice of Change (NoC) Customer Guidance explains which types of changes need to be reported to DEKRA Certification (hereafter referred to as DEKRA). It is provided to support you in managing your certifications effectively and applies to all customers with a medical device certification at DEKRA.

Changes are a natural part of a medical device's lifecycle or a medical device Quality Management System (QMS). They can occur for various reasons, such as evolving patient needs, market developments, regulatory updates, supply chain adjustments, or general business requirements. These **changes must be carefully managed and communicated** to ensure ongoing compliance and maintain the integrity of your certification.

As certificate holder, you are responsible for documenting each change, assessing its impact, and determining whether it must be reported to us. This guidance is intended to help you carry out these responsibilities.



Contents

General Overview of DEKRA's Notice of Change Handling Process	4
General Terms and Agreements	5
Certificate Holder Accountability	6
Types of Changes	7
1. QMS Changes	8
2. Administrative Changes	9
3. Adding/Removing Devices and Code Changes	10
4. Device and Type Changes	11
5. Certificate Specific Changes	12
6. Non-Reportable Changes	13
Communication	14
Annex I – Determining Reportability	15
1. QMS Changes	16
2. Administrative Changes	20
3. Adding/Removing Devices and Code Changes	21
4. Device and Type Changes	23
5. Certificate Specific Changes	31
6. Non-Reportable Changes	32



General Overview of DEKRA's Notice of Change Handling Process

The reporting of changes is based on various regulatory requirements, directives and standards, and further detailed in applicable guidance documents.

The high-level flowchart (Figure 1) provides an overview of how DEKRA handles changes and it outlines the steps you should follow when submitting changes to us.

There are two key points to consider with regard this figure:

1. Is the change considered reportable?

If yes, we need to perform a conformity assessment activity to verify the change.

2. Is pre-approval needed?

This depends on the situation. As a certificate holder, you may:

- Apply the change without our pre-approval;
- Apply the change, but we need to perform an audit or technical documentation review before updating your certificate(s) and/or Certification Notice;
- Wait for pre-approval before implementing the change.

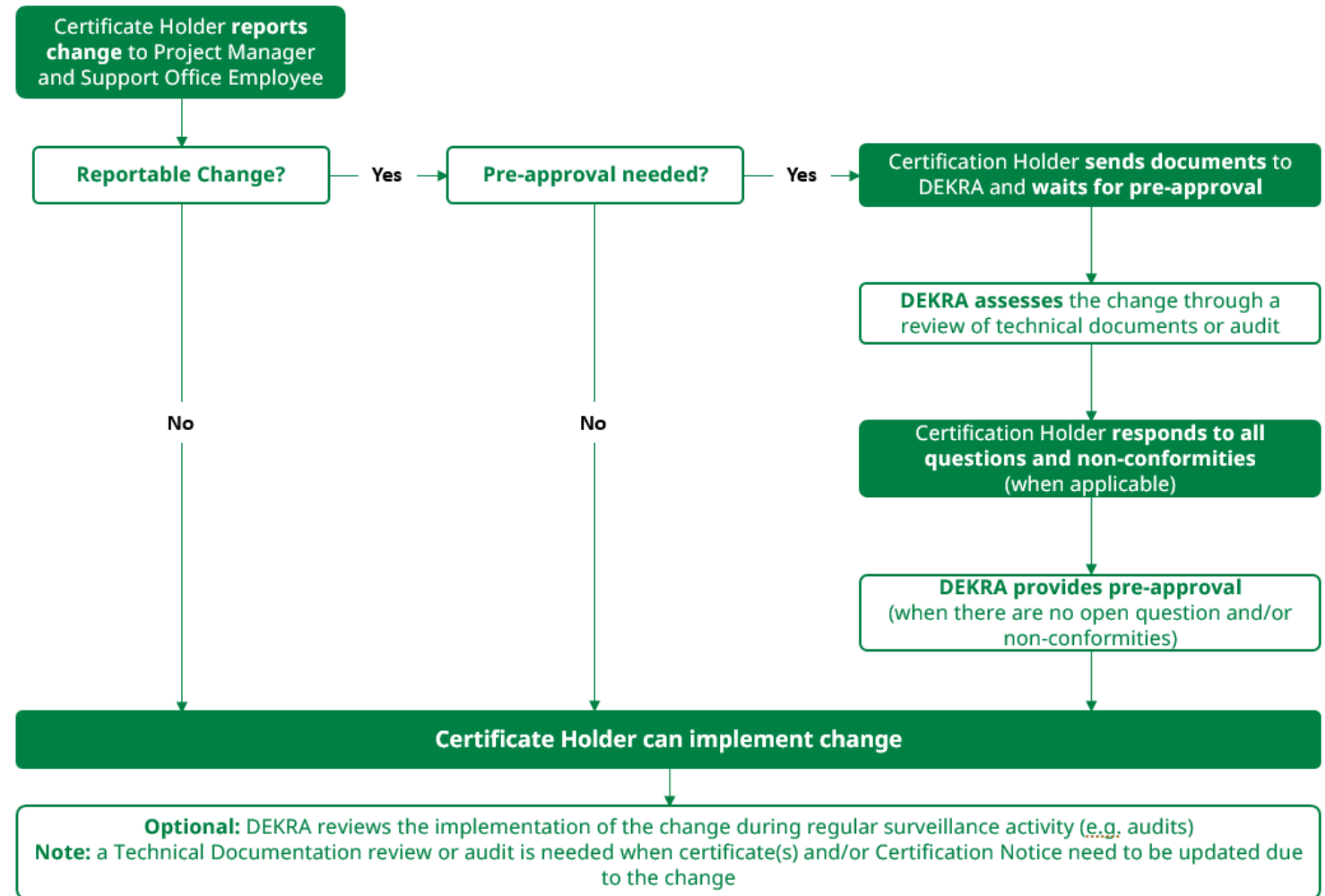


Figure 1: General process flow for Notice of Change handling



General Terms and Agreements

DEKRA has the following agreements in place to ensure that changes impacting compliance are reported. These agreements define your responsibilities:

- **General terms and conditions**

These cover general legal requirements, including the obligation to inform us about any changes that may impact conformity with relevant requirements and/or standards.

- **Medical specific certification agreement**

This agreement references the legal requirements for notifying DEKRA of changes. For MDR and IVDR, this specifically refers to the requirements outlined in Annex VII, Article 4.9 of the MDR and IVDR, which define the changes that must be reported to us.

If you are unsure whether a change needs to be reported, please contact us so we can support you in maintaining compliance.



Certificate Holder Accountability

As a certificate holder, you are responsible for ensuring that all products placed on the market comply with applicable requirements. Submitting reportable changes supports continued market access, as keeping us up to date prevents DEKRA from possibly imposing restrictions on market access.

When planning a change, you must assess it against regulatory requirements to determine the correct action.





Types of Changes

Following the general overview of our NoC process and your responsibilities as certification holder, this section focuses on the **different types of changes that should be submitted via our NoC submission form**.

For each type of change, we provide you with three key elements:

- A. Applicability**
Which certificates does this change apply to?
- B. Meaning**
What does this type of change involve?
- C. What DEKRA does**
What actions will DEKRA take after you report the change?

For more detailed examples of reportable changes per type of change, see **Annex I**.



1. QMS Changes

A. Applicability

These changes are applicable to **all** certificates.

B. Meaning

A QMS change refers to any change in your **Quality Management System**. Such a change is reportable if any of the following aspects is impacted:

- Ownership or organization;
- Site location or certificate/Certificate Notice;
- Manufacturing process, facility or equipment (including critical subcontractors);
- Sterilization, primary packaging or reprocessing process;
- Compliance of the QMS with relevant harmonized standards and/or the requirements of the directives/regulations;

For more detailed guidance on reporting QMS changes, see Annex I.

C. What DEKRA does

When you report a QMS change, **we will usually verify** it during your next audit. In some cases, we may decide to review the change earlier through a special audit, supplier audit, or technical documentation review.

You do **not need our pre-approval** before implementing the change. However:

- We can only update your certificate or Certification Notice after verification of the change;
- In case you plan to apply for a new certification scheme, we will start our application process.





2. Administrative Change

A. Applicability

These changes are applicable to **all** certificates.

B. Meaning

Administrative changes are updates that do not involve your QMS, device range, or devices themselves. However, they may still affect your certificate or Certification Notice and require an administrative update or other actions. Because of this, you **need to inform us when such changes occur**.

For more detailed guidance on reporting administrative changes, see Annex I.

C. What DEKRA does

We will update our internal records and, when necessary, your certificate and/or Certificate Notice to reflect the change. We need to verify the change before updating your certificate and/or Certificate Notice.

You do **not need our pre-approval** before implementing the change.



3. Adding or Removing Devices and Code Changes

A. Applicability

This change category is **only applicable for CE/UKCA certified devices**.

Note: For ISO certificates, if adding or removing devices impacts the certification scope, it should be reported as a QMS change.

B. Meaning

Adding or removing devices from your current certification scope or code changes. This can include:

- A new device with its own technical documentation;
- Devices added to existing technical documentation;
- Addition of devices that impact the device range on the certificates;
- Device changes that lead to a change in MDA, MDN, MDS, MDT, IVR, IVS, IVT and/or IVP codes, as mentioned in MDCG's explanatory guidance on codes.

For more detailed guidance on reporting the addition or removal of devices and code changes, see Annex I.

C. What DEKRA does

If the change is considered reportable, we will verify if **sampling** of the technical documentation (MDR/IVDR Annex IX section 2.3 and 2.4, MDR Annex XI section 10) is possible. In that case, a timely update of the certificates is assured by **an abbreviated review**. The full technical documentation will be reviewed at a later stage. If sampling is not possible, we will review the full technical documentation.

You must **wait for pre-approval** before implementing the change.

Note: your change can be reviewed and approved more quickly if you provide a draft DoC when adding a device, or a closing DoC when removing devices, together with your NoC submission form.



4. Device and Type Changes

A. Applicability

These changes are **only applicable to devices listed on TD, TE or DE certificates**.

B. Meaning

Device changes are changes that require **an update to the technical documentation of a currently CE-certified device** that may impact conformity with the General Safety and Performance Requirements (GSPRs) or Essential Requirements (ERCs).

For more detailed guidance on reporting device and type changes, see Annex I.

C. What DEKRA does

We will **review the relevant sections of your technical documentation** to assess the impact.

You must **wait for our pre-approval** before implementing the change.



5. Certificate Specific Changes

A. **Applicability**

These changes are **only applicable to specific referenced certificates/schemes**.

B. **Meaning**

These are changes that must be reported based on the **specific requirements** of one of the certificates.
For more detailed guidance on reporting scheme specific changes, see Annex I.

C. **What DEKRA does**

We will either request you to **submit a formal application** for the change or review the change during an **audit**.



6. Non-Reportable Changes

A. Applicability

Non-reportability is only applicable when the change is **not reportable for any of your certificates**.

B. Meaning

Non-reportable changes do not need to be reported, but you may still inform us for:

- Information purposes;
- Assurance that we agree the change is non-reportable.

For more detailed guidance on reporting non-reportable changes, see Annex I.

C. What DEKRA does

As a certificate holder, you may voluntarily request us to perform a conformity assessment activity and provide approval of a change. This may be useful to:

- Ensure approval at an early stage and avoid issues at a later stage. For example, DEKRA not approving a change during an audit.
- Meet requests from worldwide regulatory authorities for a documented approval of a change by DEKRA .



Communication

Maintaining certification requires timely and clear communication between certificate holders and DEKRA. To ensure compliance and avoid delays, it is essential that any changes affecting your certificate are reported promptly and through the correct process. So, good communication is key.

Reporting planned changes and submission requirements

You should inform us without delay of any planned reportable changes by submitting an official NoC submission form. When submitting a change, please ensure:

- **One change per form:**
Each NoC submission form should address a single change. A request may include multiple aspects, but combining multiple changes or product in one NoC submission form is only accepted by exception.
- **Complete, clear and traceable information:**
The information provided in the NoC submission form is complete, clear and traceable. If the submission is unclear, we will request clarification, and the you must revise your NoC submission accordingly.
- **Proper submission:**
The signed NoC submission form is submitted to a DEKRA Project Manager and Support Office Employee.
- **Supporting documentation:**
Additional documentation is submitted at the same time and clearly referenced in the NoC submission form for traceability.

Note: changes mentioned informally – for example, during audits, technical documentation reviews or meetings – do not constitute an official submission.

When in doubt

If you have questions or are uncertain about the nature of a change, we encourage you to **contact us**. We can then schedule a structured dialogue to clarify the situation and ensure a shared understanding of the impact of the change on regulatory compliance.



Annex I:

Determining Reportability

This Annex provides examples for all change categories to ease the reportability decision. Please note that the examples of what changes are reportable described in the following sections are not complete, as there are many different types of changes. So, when a change is not specifically mentioned here, try to verify it with a comparable change. In case this is not possible, please feel free to contact your Project Manager and / or Support Office Employee.

Please note that the change categories listed in this Annex are mostly based on applicable guidances.



QMS Changes

Substantial QMS changes are changes that may impact a certified QMS or its compliance and therefore require assessment by DEKRA. **All substantial QMS changes must be reported.** We will typically verify these changes during the next planned audit. Table A1 summarizes the seven main categories of substantial QMS changes and some typical examples.

Table A1: Categories and examples of substantial QMS changes (part 1).

Change Category	Examples
Ownership or Organizational changes	- Quality management personnel: modifications to the defined authority of the management representative that impact: (i) quality management system effectiveness or regulatory compliance; (ii) the capability and authority to assure that only safe and effective medical devices are released. - Change to the legal, commercial, organizational status or ownership. - Change to organization and management (e.g. key managerial, decision-making or technical staff).
Changes impacting site location(s) or certificate/ Certification Notice content	- Changes to legal manufacturer name and/or address. - Addition or alternate/new facility, site or contact address including critical subcontractors. For example, relocation of the manufacturing operation of a critical process or device to a new site or centralizing the design and/or development functions for several manufacturing sites. - Name and address on the device labelling stays the same but a new manufacturing facility is added, or production facilities are moved (only for CE manufacturers). - ISO scope of operations for the certified management system - Impacting the area of application (e.g. neurology, cardiovascular, dental); - Product related: adding types of devices / device categories e.g. addition of sterile single use dialysis sets to an existing scope limited to hemodialysis equipment, or the addition of magnetic resonance imaging to an existing scope limited to ultrasound equipment; - Addition or removal of activities (e.g. adding servicing). - Removal of manufacturing facility. - Transfer of activities (design, manufacture, storage, etc.) from one site to another, within the company/group or to an external service provider. - Critical subcontractor loses QMS certification that is mentioned on the Certification Notice - Change in the intended purpose that is mentioned on a certificate



QMS Changes

Table A1: Categories and examples of substantial QMS changes (part 2).

Change Category	Examples
Change to manufacturing process, facility or equipment (including critical suppliers)	- Changing a test acceptance criterion (unless tightened criteria) or test method or removal of test acceptance criteria, in-process inspection, or final inspection. - Implementation of new technologies or different processing solvents (e.g. oils, transport rollers altering the handling of components) in the manufacturing process (MDT / IVT or MDS / IVS code) of the facility relocation to a different site. - New processes, process changes: significant modifications to special processes (e.g. change from glueing to welding). - Moving a production line from in-house to an outside facility (manufacturer’s own or a contractor); introducing a production line into manufacturer’s own facility from an outside facility. - Changes to the production process or modification of the production environment (e.g. production technology, equipment, clean room, and controlled environment, new equipment), which may affect the compliance with the GSPRs (e.g. building a new cleanroom, classification of the environmental controlled area is going up). - Change in a manufacturing process affecting the concentration and composition (i.e. formulation) of reagents for an IVD medical device, which may impact the active components in the assay, and hence the device performance and stability. - Addition of a new production line or modification of line likely to have an impact on the safety and/or performance of the device(s). - Production process change impacting biocompatibility of materials being manufactured (e.g. solvents used as process aids in production are changed, or device specifications by wider manufacturing tolerances). Note: changes that also impact codes applied (e.g. MDT, IVT, MDS, IVS, IVP) should also be reported as a code change. Critical suppliers - A critical supplier’s manufacturing process, technology, facility or equipment changes, requiring new performance qualification. - Introduction, change (including alternative critical supplier), removal of a critical material supplier; critical component/process subcontractor. - A new supplier with different quality control measures, testing methods, or acceptance criteria, impacting product conformity and traceability.



QMS Changes

Table A1: Categories and examples of substantial QMS changes (part 3).

Change Category	Examples
Change to manufacturing process impacting sterilization, primary packaging or reprocessing (examples for this category continue the next page)	Sterilization and primary packaging: • Changes to the packaging process, which is a component of manufacturing, which could affect sterility and stability of the device. • Changes in the density or configuration of the sterilization load. • Changes to the quality control verification and validation process such as introducing parametric release. • Changes in packaging characteristics of a sterile medical device, configuration or density could affect the absorption or penetration of the sterilant, the residue levels (where applicable) and the effectiveness of the sterilization process in addition to the safety of the sterile device. Issues of compatibility between the packaging material and the sterilization process must also be taken into consideration to ensure that seal integrity is not affected and that the packaging preserves the functionality and safety of the device throughout its declared shelf-life. • Making substantial changes to the sterilization process/cycle that would necessitate a full new validation (e.g. going from EtO sterilization to gamma sterilization). • Change increasing the alert level of bioburden or action levels or that cause the detection of an organism that is more difficult to eliminate. • Changes in the sterilization process (e.g., equipment, cycle parameters, density or load configurations) • Changes in the sterilization modality/technology/method or process. • Change of the sterilization service provider. • Reductions in incubation conditions of biological indicators. • Change in the resistance profile of the product bioburden (e.g. due to changes in the manufacturing environment or change of manufacturing location). • Changes to sterilization revalidation criteria. Reprocessing: • Changes of the limitation of maximum reprocessing cycles in the IFU from a distinct number of cycles to unlimited reprocessing or increase of the maximum number of cycles. • Claim of a new reprocessing technology in the IFU (e.g. addition of plasma sterilization). • Omission / addition of process steps (cleaning / disinfection / sterilization).



QMS Changes

Table A1: Categories and examples of substantial QMS changes (part 4).

Change Category	Examples
Change to manufacturing process impacting sterilization, primary packaging or reprocessing (Continued)	• Changes of the QMS procedures and processes relating to reuse including changes in: ◦ Provisions for validation of reprocessing (cleaning, disinfection, sterilization, lifetime including biocompatibility and functionality): endpoints, acceptance criteria, changes of the systematic grouping approach for the section of the master device; ◦ Provisions for handling of changes: if new validation is needed or if the existing validation cover the new situation for: ▪ New or changed device; ▪ Change in reprocessing chemistry (detergent, disinfectant – is a new cleanability study and lifetime test data needed, e.g. if cleaning process is changed from enzymatic to highly alkaline cleaning); ▪ Release criteria for implementation of changes relating to reuse; ▪ Measures to be taken depending on market data relating to reuse. • Changes of the systematic grouping approach for the section of the master device with regards to reuse validation. • Changes to the IFU such as described detergent type or concentration, e.g. impacting prion decontamination.
Change impacting compliance of the QMS with relevant harmonized standards and/or the requirements of directives/regulations	• Major changes to the management system and processes. For example, extension to manufacturing and/or design control, change in design verification and/or validation or changes in the process interactions or quality control procedures. • Making substantial changes to the structuring of the quality system. • Archiving from paper to electronic storage or regular labelling to e-labelling. • Buying a product design from a subcontractor, that falls within the manufacturers own approved product range, but which was not designed under the manufacturer’s own design control system. • Changes in the QMS to comply to standards, regulations to which the certificate holder is certified, including changes to post market surveillance, vigilance procedures. • Change significantly impacting compliance of QMS with regulatory requirements (e.g. vigilance processes, design processes) or a complete re-write of QMS procedures, impacting processes. For example, a new system for risk management impacting risk acceptability criteria or negatively impacting the risk benefit rationale, software design process from waterfall to Agile. • Change to using AI tools as QMS software
Not reportable	• A change in a manufacturing process that will need process validation, but does not affect the product specifications including tolerances, does not necessarily affect performance. (NBOG) • Addition of a supplier for electrical components, e.g. for resistors, to the list of approved suppliers. The components to be supplied meet the manufacturer’s existing specifications and do not fall within the manufacturer’s classification of a “substantial change”.



Administrative Changes

Administrative changes include all changes that are not related to the QMS, device range, or a specific device, but still require action from DEKRA. **All administrative changes must be reported.** However, there are different categories of administrative changes, and each category is processed in a different way (Table A2).

Table A2: Administrative changes.

Administrative Change Category	Examples
Administrative change impacting certification documents	• Editorial change on certificate or certification notice related content. • Change of authorized representative, MDSAP correspondents, TCP distributor or UK responsible person details (e.g. name and/or address). • Change of legal entity or name (and SRN) without Organizational modification of the company; Change of using AG in the company name (German area of Switzerland) to SA (French abbreviation for Société Anonyme) for a Swiss company. • Change in address without relocation. • Request for issuance of multiple certificates to separate categories/generic groups of devices or references previously covered under one single certificate. • Change or addition of device brand name when it is reported on the certificate. • Cosmetic rephrasing the certification scope wording, without changing of the category/generic device-group certified (no actual changing in the scope of the certified QMS). • Merger of companies without Organizational change of the legal manufacturer. • Change in the name of a supplier. • Change in Basic UDI-DI.
Other administrative change	• Changes to managerial personnel, Person Responsible for Regulatory Compliance (PRRC), to the EU authorized representative (NBCG), Quality Management Board. • Major changes in workforce size: adjustments in the number of employees at a facility (e.g. due to hiring, layoffs, or organizational restructuring) since the last audit. Smaller changes in FTE will always be asked for in advance of an audit. • Changes in the user interface (e.g. portals used for transferring data to and from the Notified Body rather than e-mails). • Additional office space within the same building with the same address. • Change in number of shifts. • Change to Contact persons (point of communication). • Changes to VAT number.
Non-reportable administrative changes	• Critical subcontractor certification renewal. • DoC updates not related to a reportable change. Note: these updates are verified during the regular DEKRA audit

Adding/Removing Devices and Code Changes

CE/ UKCA certified devices

When devices are to be added or removed from the current certified scope, including device range changes, **these must be reported to us**. The processing requirements depend on the nature of the change. Table A3 summarizes the main categories and examples.

Table A3: Device range changes and typical examples (part 1).

Change Category	Examples
Addition of a new device to new technical documentation or existing technical documentation	New device or removal of existing certified devices DEKRA must maintain an overview of your technical documentation for various reasons. Therefore, we need to know if added devices are mentioned on new technical documentation or not. Note: the addition of a devices can be reviewed and approved more quickly if you provide a draft DoC along with your NoC submission form. Addition of the following devices require TD or TE certification: - AIMD, Class III or MDR class IIb implantable (except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors). - List A, class B (Near patient testing / Self-testing), class C (Near patient testing / Self-testing / Companion diagnostics) or class D devices. Addition of the following devices impacts the device range and is typically not allowed via sampling: - Addition of a device category (Class IIa, Class B) or generic device group (Class IIb, Class C) to the certificate: this includes introducing a new device category or a generic device group of medical devices requiring certification. MDCG guidance on sampling can be used for clarification. - For Class IIb and C: sampling is allowed when the EMDN description is different due to an update of EMDN codes on the official list. Please note that the applied EMDN code is to be corrected at the next recertification or as part of the device addition. - Class IIb (rule 12) active devices intended to administer and/or remove a medicinal product require a clinical evaluation review before these can be added to the sampling plan. - Class Is, Im and/or Ir, when the sterilization technology is not yet sampled by DEKRA. Addition of the following devices is allowed via sampling: - Addition of a new Class IIa, Class B or Class C, IIb not implantable device under an existing device category/generic device group. MDCG guidance on sampling can be used for clarification. - MDR: Addition of a new Class IIa, Class B or Class C, IIb not implantable device under an existing device category/generic device group. - Class Is, Im and/or Ir, when DEKRA’s sampling criteria are fulfilled. Note: certification of devices can only be started when a device in an existing device category/generic device group is already on the QMS certificate.

Adding/Removing Devices and Code Changes

CE/ UKCA Certified Devices

Table A3: Device range changes and typical examples (part 2).

Change Category	Examples
New device or removal of existing certified devices	
Removal of an existing device from the certified scope	Removal of a device category or generic device group: the withdrawal of individual devices or entire groups must be reported as a substantial change. Note: the removal of a devices can be reviewed and approved more quickly if you provide a closing DoC together with your NoC submission form.
Change in device code, nomenclature or classification applied	• Device change leading to a change in MDA, MDN, MDS, MDT, IVR, IVS, IVT or IVP codes as mentioned in MDCG explanatory guidance on codes. • Change in applicable EMDN codes as mentioned on the certificates. • Change in device classification.
No devices are added or removed	Models are added but models are not specifically mentioned on the DoC, certificate or CN. For example, an article number is added to sterile surgical sets, washing sets, tubing for blood administration sets that does not impact sterilization or packaging load configuration.



Device and Type Changes

(For Devices on TD, TE or DE Certificates)

Product design changes include changes that may impact the device’s design, performance, safety, intended purpose or compliance with applicable requirements. Such **product design and type changes must be reported** to DEKRA and will be assessed to determine whether they affect conformity or require pre-approval. Table A4 summarizes the main categories and provides some typical examples.

Table A4: Categories and typical examples of product design and type changes (part 1).

Change Category	Examples
Risk Management	• New hazards are introduced which have not previously been addressed. • Analysis of new risks introduced due to the change performed with the need to have additional control means. • Analysis of an already identified risk that is negatively impacted by the change. • Risk-benefit profile is changed. • Risk management criteria are changed.
Compliance to GSPR’s/ERC’s and evidence of conformity	• Change driven by the development of the state of the art. • Change impacting safety and performance requirements (GSPR). • The change impacts new or changed standards or common specifications used to demonstrate compliance to the GSPR’s or ERC’s. • The change impacts referenced evidence documentation to demonstrate compliance to the GSPR’s or ERC’s.
Electrical safety and EMC (incl alarm systems) and MRI compatibility	• Changes of main components like power source, Central Processing Unit (CPU), defibrillator-capacitors. • Changes in critical components or widening specification limits. • Changes in alarm system. • Changing critical components (as mentioned in the critical components list of the electrical safety test report). • Changing design that impacts compliance to electrical safety and EMC (broadening specifications of non-critical components, decreasing critical distances between components). • Materials that are critical for MR compatibility are changed (supplier or material formulation).
Usability	• Device will have different end users or will be used in a different manner or different environment. • Change in ergonomics of patient user interface. • Analysis of further usability data, e.g. human factors studies.



Design and Type Changes

(For Devices on TD, TE or DE Certificates)

Table A4: Categories and typical examples of product design and type changes (part 2).

Change Category	Examples
Verification & validation (device specification)	• Changes impacting performance specification of the device. These can be the result of a safety issue. • Almost all changes in the control mechanism of a device raise questions of safety and performance. Control mechanisms are a mean of verifying or checking that the specifications or outputs of the device meet a standard or predetermined result. They are mechanisms put in place to maintain on-going control or regulate the output of a device (e.g. internal calibration of active devices). • Changes to the operating principles (such as those resulting from the use of new materials or a change in the source or type of energy used by the device) are usually considered substantial and often impact labelling. For example, under IVDR, a change from immunofluorescence to ELISA would fall into this category. • Changes to design specifications—such as physical, dimensional, or environmental aspects—may be considered reportable if they: • affect the indications or contraindications for use; • require additional clinical data; • raise new safety and performance issues or affect the performance; • requires warnings to ensure safety and performance for the intended use of the device. . • MDR: changes in materials within a single generic material type or changes in formulation that affect the chemistry, metallurgy or other property, such as stability, of the device. • MDR: changes in materials impacting design and/or performance specifications. • IVDR: changes to materials in an IVDD, which often affect its performance characteristics, including specificity or sensitivity • IVDR: changes to materials that may affect the operating principle of an IVDD include modifications to reaction components or materials, such as calibration substances or changes to methods like specimen pre-treatment, incubation times, or temperatures. These changes are generally considered significant if they lead to altered performance characteristics that are reflected in the labelling. • Change in the diameter/French size of a catheter that potentially affects the flow rate and thus performance. • Change in the design of a product, that leads to new specifications and affects the essential requirements. • Changes which affect the design, performance/characteristics of the device, or safety (e.g. new welding method). • IVD reagents: changes which could significantly influence the performance characteristics compared to those of the originally approved design. This can be due to a change in the manufacturing process. • Changes in the design of the device, such as device shape or dimension and characteristics outside current specifications. • Changes in critical components or widening specification limits. • IVDR: changes to components or materials (e.g. change of calibration materials), or to methods such as the pre-treatment specimen, incubation times and temperatures, which may potentially affect the principle of operation of an IVD device.



Design and Type Changes

(For Devices on TD, TE or DE Certificates)

Table A4: Categories and typical examples of product design and type changes (part 3).

Change Category	Examples
Software	• A software change that impacts the control of the device and may alter the diagnosis or therapy delivered to the patient. • An alteration in software that modifies an algorithm impacting the diagnosis or the therapy delivered. • A software change that affects how data is read or interpreted by the user, which could alter the treatment or diagnosis of the patient when compared to the previous software version. • A software change that replaces previously required user input to a closed loop decision. • Addition of a new feature to the software that may change the diagnosis or the therapy delivered to the patient. • Introduction to or removal of a (new) alarm function in the software, where the response to the new configuration could change the treatment of the patient in comparison to the previous software version. • A software change that incorporates a significant change to the operating system on which the software runs. • A software change to correct an error which might have led to safety risks for the patient (e.g. the software change is a corrective/preventive action following a recall/field safety action). • Computer software (e.g. new functionalities, new algorithms for computing) which will change the specifications and/or performance of the device. • New operating system. • Changes to the platform and/or interface type (e.g. from PC to tablet, or from mouse to touch). • Artificial Intelligence retraining that impacts how the software performs. • Changes to the intended purpose (including new algorithms). • Major software version changes. • Introduction of new technology (e.g. replacement of a deterministic algorithm with an AI/ML-based algorithm). • Addition of a measuring function as per GSPR 15. • Wide-ranging changes/addition/removal of core software features that may impact safety and performance of the device. • Complete “re-write” of a SaMD (e.g. change from one programming language to another). • Porting an application from one operating system to another operating system (e.g. iOS to Android or vice versa). • Essential Manufacturing Characteristics. For example, changing software distribution mechanisms, like changing distribution via physical media to an app store”, or vice versa, or changing from distribution via a consumer-grade “app store” to an ISO 13485-certified cloud platform, or vice versa.



Design and Type Changes

(For Devices on TD, TE or DE Certificates)

Table A4: Categories and typical examples of product design and type changes (part 4).

Change Category	Examples
Sterilization	• Device design and material changes that introduce a feature that is more difficult to sterilize. • Changes to the quality control verification and validation process such as introducing parametric release. • Change from non-sterile to sterile device. • Change of sterilization methods, process or parameters (e.g. from a device sterilized by irradiation to sterilization with ethylene oxide). • Change of material of the device having an impact on sterilization (e.g. addition of a new material that retains a larger quantity of residues of ethylene oxide). • Change in the design of the device having an impact on the sterilization (e.g. change of lumen dimension for an aspiration catheter or a drip chamber for an infusion set). • Change in packaging impacting sterilization validation (e.g. adversely affecting the permeability of the packaging to sterilizing agents). • Change in packaging configuration affecting the presentation of the load to the sterilizer. • Change in the resistance profile of the product bioburden. • In case the relevant standards require a revalidation of the sterilization process the change is considered as reportable.
Reprocessing	• Changes to the IFU, such as described detergent type or concentration (e.g. impacting prion decontamination). • Adding new devices as adoption to an existing device group within an already certified device category or generic device group. • Change of the limitation of maximum reprocessing cycles in the IFU from a distinct number of cycles to unlimited reprocessing, or an increase of the maximum number of cycles. • Claim of a new reprocessing technology in the IFU (e.g. plasma sterilization). • New validation or re-validation criteria. • New or changed device for reprocessing. • Changed release criteria.
Packaging	• Changes in packaging characteristics of a sterile medical device, configuration or density, which could affect the absorption or penetration of the sterilant, the residue levels (where applicable) and the effectiveness of the sterilization process in addition to the safety of the sterile device. Issues of compatibility between the packaging material and the sterilization process must also be taken into consideration to ensure that seal integrity is not affected and that the packaging preserves the functionality and safety of the device throughout its declared shelf-life. • Change in the packaging configuration that affect protection against transportation or that might affect maintenance of sterility during shelf life. • Change to claimed shelf life.



Device and Type Changes

(For Devices on TD, TE or DE Certificates)

Table A4: Categories and typical examples of product design and type changes (part 5).

Change Category	Examples
Biocompatibility or absorbed or locally dispersed device aspects	• Changes of the materials that come in contact with the body of patients or other users of the device. • MDR: if the device is a surgically invasive device intended to be absorbed by the body or to remain in the body for at least thirty consecutive days, and the altered material would be in contact with body tissues or fluids • MDR: in cases where devices are not intended to be absorbed by the body or to remain in the body for at least 30 consecutive days, but where the altered material is in contact with body tissues or fluids, an approval by DEKRA is required unless the new material meets the existing specifications. • Changes of materials that must be biocompatible. • Change in material supplier that potentially affects biocompatibility • MDR: changes to an ingredient or material (from a new or existing supplier) that do not meet existing specifications and/or acceptance criteria. • MDR: for implantable devices, changes to materials that are not produced to an established standard/specification (e.g., ASTM standards). • MDR: changes to material formulation affecting specifications, stability or biocompatibility of the finished device. • MDR: changes affecting biological safety and/or chemical, physical or electrical properties of the finished device, or any other device characteristics, such as stability, including transportation.
Labelling	• Changes to the intended use or indications for use. • A limitation to the indications for use is introduced because of concerns associated with the safe and effective use of the device, and a contraindication must be added. • Addition or removal of a contraindication such as “not for pediatric use”, or removal of a warning or precaution • A change in the shelf life is considered a substantial change, and an approval by the Notified Body is required, when the protocols and methods for determining shelf life have been changed or have not been reviewed in a previous approval. • Changes to the IFU impacting packaging and/or sterilization validation (e.g. addition of new languages). • Clinically or technically relevant changes such as dimension, key performance indicators, intended purpose, shelf life, indications, contraindications and/or warnings/precautions. • IVDR: changes to materials that impact performance characteristics reflected in the labelling. • Change in manufacturer name. • Change introduced by reprocessing or sterilization aspects (e.g. sterilization method change, number of allowed re-processing cycles, detergents used).



Device and Type Changes

(For Devices on TD, TE or DE Certificates)

Table A4: Categories and typical examples of product design and type changes (part 6).

Change Category	Examples
Manufacturing information (process, facility or equipment) incl critical suppliers.	• Changes of suppliers. • Changes relating to a manufacturing process, facility or equipment that impact the product’s safety or performance. • Changes to the manufacturing process, facility, or equipment that affect the safety or performance of a device are considered substantial. For example, this may include changes to the packaging process, which is part of manufacturing. • Critical supplier’s manufacturing process, facility or equipment changes. • Changing or removing a test acceptance criterion, test method, in-process inspection, or final inspection. • New welding method. • Changes in the manufacturing process, including quality control specifications, impacting the design and performance specifications. • Changes to specification of final Quality Control affecting batch verification of class D IVDs. • Changes that may affect the verification of manufactured batches of class D devices such as changes to manufacturing, raw materials (ingredients, formulation etc.), equipment, quality control, transport or storage. • Changes to scientific, technical or clinical information which has come to manufacturer’s knowledge, impacting scientific or technical validity of the batch verification testing of class D device (e.g. new variant strain for microbiological assays or knowledge of new interfering or cross-reacting substances). • Change of plant-origin materials incorporated in a device when their synthesis and manufacturing process differs from that approved for the device. • MDR: changes to materials in contact with body fluids or tissues, or components / substances which are absorbed or locally dispersed in the body. • Changes impacting process validations. • Changes in test method, test acceptance criteria, in process inspections and final inspections Note: please also verify impact on biocompatibility and sterilization in case of manufacturing changes
Clinical/ performance evaluation (intended use or claims made to the device) (examples for this category continue the next page)	• Changes of the intended purpose, conditions for use or the details on intended use of the device. • Change in the indications or contraindications for use or warnings necessary to ensure safety and efficacy for the intended use of the device. • A change meaning that the clinical data or performance evaluation data for the original device is not sufficient to assure conformity of the changed device with the required characteristics and performance. • Changes to the conditions prescribed for the use. • Change to intended purpose and/or suitability of companion diagnostic devices in relation to the medicinal product. • Changes in clinical conditions or addition of a new clinical condition. • Changes in the target population (e.g. change from adult to pediatric population) or addition of a new target population.



Device and Type Changes

(For Devices on TD, TE or DE Certificates)

Table A4: Categories and typical examples of product design and type changes (part 7).

Change Category	Examples
Clinical/ performance evaluation (intended use or claims made to the device) (continued)	• Change in anatomical site or addition of anatomical site. • Change in the delivery pathway or deployment method. • Change in instructions on how to use the device (e.g., change in instructions on the preparation of the device, implantation technique or device deployment technique). • Change or removal of contraindications (e.g. such as “not for pediatric use”), warnings or precautions. • Limitations of the intended purpose or clinical application such as restriction or deletion of certain therapeutic indications, or applications, or target population. • Minor changes to clarify the existing wording of the warnings and precautions for a device when these changes add or remove a contraindication or remove a warning or precaution. • Analysis of further clinical data (e.g. device related performance data, clinical investigation, post-market clinical data), to support the safety and performance of the altered device. • Change in PMCF/PMPF plan. • IVDR: changes to materials requiring the testing of additional clinical samples to determine the performance characteristics of an IVD device, unless the additional clinical trial confirms only that the changed IVD device still meets the performance specifications approved and labelling changes are not required. • For Class D IVD Device: changes affecting performance claimed by the manufacturer or compliance with the Common Specifications or with other solutions chosen by the manufacturer
Substance incorporated in or utilized for the manufacturing of a device (e.g. companion diagnostics, medicinal substances, tissues or cells of human or animal origin or their derivatives) (examples for this category continue the next page)	• Changes related to tissues or cells of animal origin, or their derivatives, such as from TSE susceptible species, as referred to in Regulation (EU) No 722/2012. • Changes related to substance, as an integral part of the device, which, if used separately, may be considered a medicinal product within the meaning of point 2 of Article 1 of Directive 2001/83/EC. • Changes related to medicinal products derived from human blood or human plasma that have an action ancillary to that of the device. • Changes related to derivatives of tissues or cells of human origin as an integral part of the device covered by Directive 2004/23/EC, particularly changes relating to their donation, testing or procurement. • All changes to the sourcing or processing of materials of human origin or substances, which, if used separately, may be considered a medicinal product • Changes of the geographical source of animals, the raw materials of animal origin, and the processes for selection, collection, handling, control and inactivation/elimination that may modify viral safety.



Device and Type Changes

(For Devices on TD, TE or DE Certificates)

Table A4: Categories and typical examples of product design and type changes (part 8).

Change Category	Examples
Substances incorporated in or utilized for the manufacturing of a device (e.g. companion diagnostics, medicinal substances, tissues or cells of human or animal origin or their derivatives) (continued)	• Tissues (or derivatives) derived from species concerned by regulation (EU) No 722/2012: changes regarding tissues (or derivatives), processes for selection, collection, processing, handling, inactivation and elimination or any new data collected by the manufacturer that is relevant to the medical device regarding TSE risk • Changes to materials of human, animal, or biological origin (e.g., changes in geographical origin of animals, raw materials, or processes such as selection, collection, handling, control, and viral inactivation/elimination that could impact safety). • Change in patient's exposure to materials of human, animal, or biological origin or medicinal substance or substances of concerns (substances which are carcinogenic, mutagenic or toxic to reproduction or substances having endocrine-disrupting properties). • IVDR: For Companion Diagnostic IVD Device - Changes affecting the performance and/or the intended use and/or the suitability of the device in relation to the medicinal product.
Type examination changes	
Approved type of a device	• Changes (limitation or extension) to the intended purpose and conditions. • Changes impacting the original type tests used for CE approval. • Other changes to the approved device that may affect conformity with the general safety and performance requirements.
Non-Reportable Changes	
Non-reportable	• Tightening of design specifications within specified tolerances and where there is no creation of new features. • If a software change is only intended to correct an inadvertent logic error that does not pose a safety risk and brings the system back into specification. • A software change that only introduces non-therapeutic and/or non-diagnostic features such as printing, faxing, improved image clarity, reporting format or additional language support. • A software change that only modifies the appearance of the user interface with negligible risk of impacting the diagnosis or therapy delivered to the patient. • A software change that disables a feature that does not interact with other features. • Changes made to device labelling solely for the purposes of clarifying instructions to make the device easier, safer or more effective to use (e.g. modifications in language and structure to be used by a lay person).



Scheme/Certificate Specific Changes

For some specific certification schemes, the certification holders is required to report specific types of changes. These are summarized in Table A5 below.

Table A5: changes that need to be reported for specific certification schemes.

Change Category	Examples
MDSAP: Substantial change related to device(s) placed on the Australian market.	• A proposed change to the QMS, including the name of location of the manufacturer. • A proposed change to critical suppliers or the goods and services they provide. • A proposed change to a validated manufacturing process. • Changes relating to class III or AIMD devices. • Change to the design or intended purpose. • Change to the packaging, storage or transport conditions require DEKRA assessment
MDR/IVDR Article 16 certificate. Audit and pre-approval required	• Addition of translation/labelling to the scope. • Addition of repackaging to the scope. • Addition of new types of devices.
legacy device (MDD/IVDD/AIM DD device)	MDCG 2020-03 (MDR) or MDCG 2022-06 (IVDR) is to be used to assess the significance of the change according Article 120 of the MDR/IVDR. If the change is not significant, a DEKRA impact assessment shall be performed by reviewing all aspects outlined in the sections above (QMS substantial changes, administrative changes, device range changes, or device-specific changes.
Request for NB opinion (Article 117)	No further clarification.
SS(C)P editorial changes	Typo corrections made to the SSCP.
SS(C)P change needing DEKRA validation	• Change in intended purpose and conditions for use. • Change in claims. Typically, this is related to a device related change



Non-Reportable Changes

As a certification holder, you can decide to send a non-reportable change to DEKRA for information purposes. Based on this information, we will assess whether this change needs to be reviewed during the next audit or if certain technical documentation should be sampled.

For example, a certification holder with a class IIa device, may change this device in such a way that all design documentation is updated. Although this device would formally not be a new device, the DEKRA Project Manager could decide to add the updated technical documentation for surveillance review. Also, during audits, DEKRA may determine that a specific device should be reviewed, depending on the impact of the change.

In addition, you can ask us to review and approve a change. This can help ensure that your change is accepted and prevent potential issues later, such as DEKRA not approving a change. It may also be requested to comply with the requirement of regulatory authorities worldwide. In such cases, we will initiate conformity assessment activities to support you.

