# Renewals

MDR+IVDR+UKCA

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2024-10-10

# Agenda

01 Why are we doing renewals?

02 The BSI Process

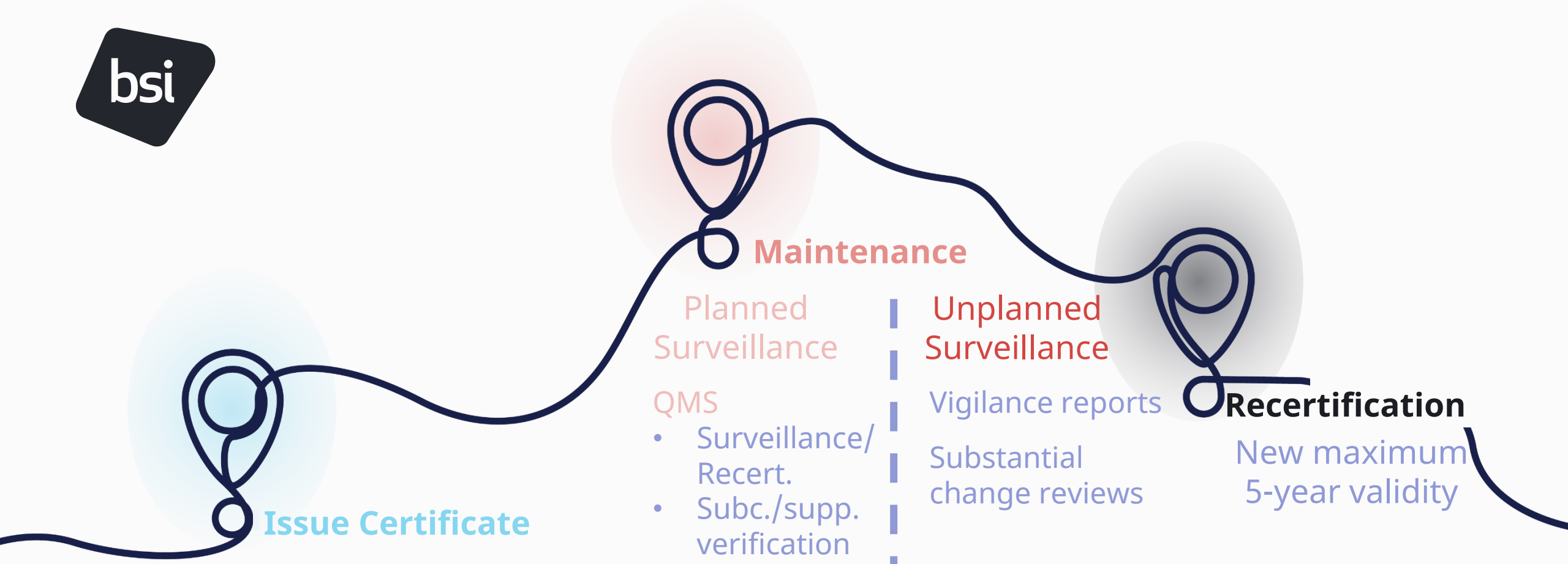
03 Quality Certificates

04 Product Certificates

05 Clinical Evaluations

06 What to look out for?

# Why are we doing renewals?



## Issue Certificate

Maximum 5-year validity

## Maintenance

### Planned Surveillance

QMS
- Surveillance/ Recert.
- Subc./supp. verification audit

Microbiology

Technical
- TD Sampling
- PSUR

UAV

### Unplanned Surveillance

Vigilance reports

Substantial change reviews

## Recertification

New maximum 5-year validity

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# Requirements - MDR/IVDR

Annex VII 4.11

4.11. Re-certification

The notified body shall have documented procedures in place relating to the re-certification reviews and the renewal of certificates. Re-certification of approved quality management systems or EU technical documentation assessment certificates or EU type-examination certificates shall occur at least every five years.

The notified body shall have documented procedures relating to renewals of EU technical documentation assessment certificates and EU type-examination certificates and those procedures shall require the manufacturer in question to submit a summary of changes and scientific findings for the device, including:

(a) all changes to the originally approved device, including changes not yet notified,

(b) experience gained from post-market surveillance,

(c) experience from risk management,

(d) experience from updating the proof of compliance with the general safety and performance requirements set out in Annex I,

(e) experience from reviews of the clinical evaluation, including the results of any clinical investigations and PMCF,

(f) changes to the requirements, to components of the device or to the scientific or regulatory environment,

(g) changes to applied or new harmonised standards, CS or equivalent documents, and

(h) changes in medical, scientific and technical knowledge, such as:

— new treatments,

— changes in test methods,

— new scientific findings on materials and components, including findings on their biocompatibility,

— experience from studies on comparable devices,

— data from registers and registries,

— experience from clinical investigations with comparable devices.

The notified body shall have documented procedures to assess the information referred to in the second paragraph and shall pay particular attention to clinical data from post-market surveillance and PMCF activities undertaken since the previous certification or re-certification, including appropriate updates to manufacturers' clinical evaluation reports.

For the decision on re-certification, the notified body in question shall use the same methods and principles as for the initial certification decision. If necessary, separate forms shall be established for re-certification taking into account the steps taken for certification such as application and application review.

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# Requirements - MDR/IVDR

MDCG 2019-6 Rev 4

**IV.12. What are the applicable requirements for re-certification?**

Conformity assessment activities to be carried out in case of renewal of certificates/re-certification are laid down in Article 56(2) of the MDR / Article 51(2) of the IVDR, where the Regulations establish that the notified body can extend the validity of the certificate for further periods based on a re-assessment in accordance with the applicable conformity assessment procedures (i.e. as described in annexes IX-XI). In addition, Section 4.11 of Annex VII states that the notified body must use the same methods and principles for the decision on re-certification as for the initial certification decision.

While for EU Technical documentation assessment certificates and EU type examination, Section 4.11 of Annex VII establishes a targeted conformity assessment (i.e. focusing in certain elements of the technical documentation review), this is not the case for the quality management system certificates.

The notified body will ensure that all relevant Regulation requirements for conducting audits (i.e. those covered in Section 4.5.2 of Annex VII, and sections 2.2 and 2.3 of Annex IX) are assessed in its entirety at least once after issuing the certificate and before its expiry date. In addition, prior to the renewal of a QMS certificate, it is required that the notified body will assess the results of the surveillance audits carried out during the period of validity of the certificate in accordance with section 4.10 of Annex VII, also including any unannounced audits and all audits carried out at subcontractors and suppliers.

This review must include the manufacturer´s system for vigilance, post-market surveillance, PMCF and risk management as well as all open non-conformities Furthermore, results of the notified body´s evaluation of additional scientific and clinical data and clinical evaluations and post-market information as well as the outcome of latest technical documentation assessments on sampling basis and product tests have to be considered.

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# Requirements - UKCA

UKCA regulation mirrors MDD (Article 11) / IVDD (Article 9)

**MDD Article 11 Section 11**

11. Decisions taken by the notified bodies in accordance with ►M5 Annexes II, III, V and VI ◄ shall be valid for a maximum of five years and may be extended on application, made at a time agreed in the contract signed by both parties, ►M5 for further periods of a maximum length of five years ◄.

**IVDD Article 9 Section 10**

10. Decisions taken by the notified bodies in accordance with Annexes III, IV, and V shall be valid for a maximum of five years and may be extended on application, made at a time agreed in the contract signed by both parties, for further periods of up to five years.

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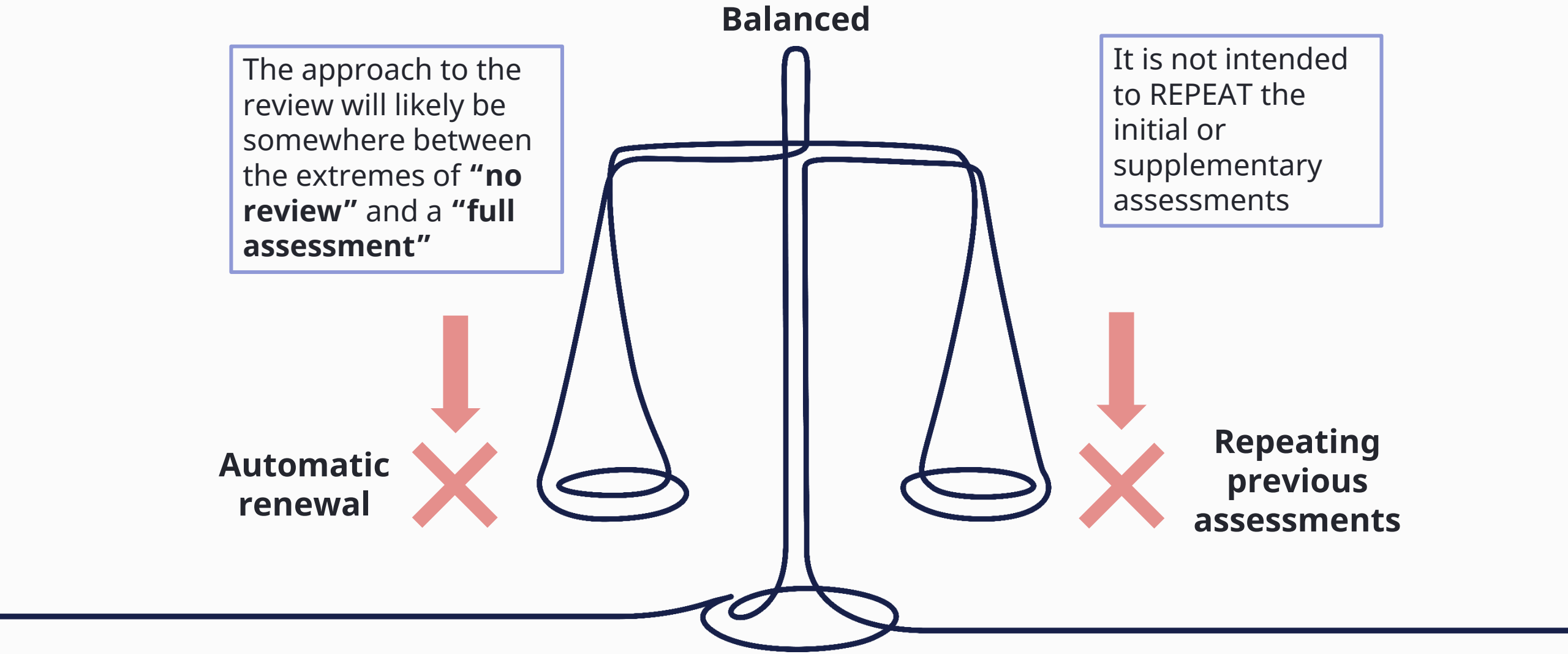
# What is our Approach?

The approach to the review will likely be somewhere between the extremes of **“no review”** and a **“full assessment”**




It is not intended to REPEAT the initial or supplementary assessments

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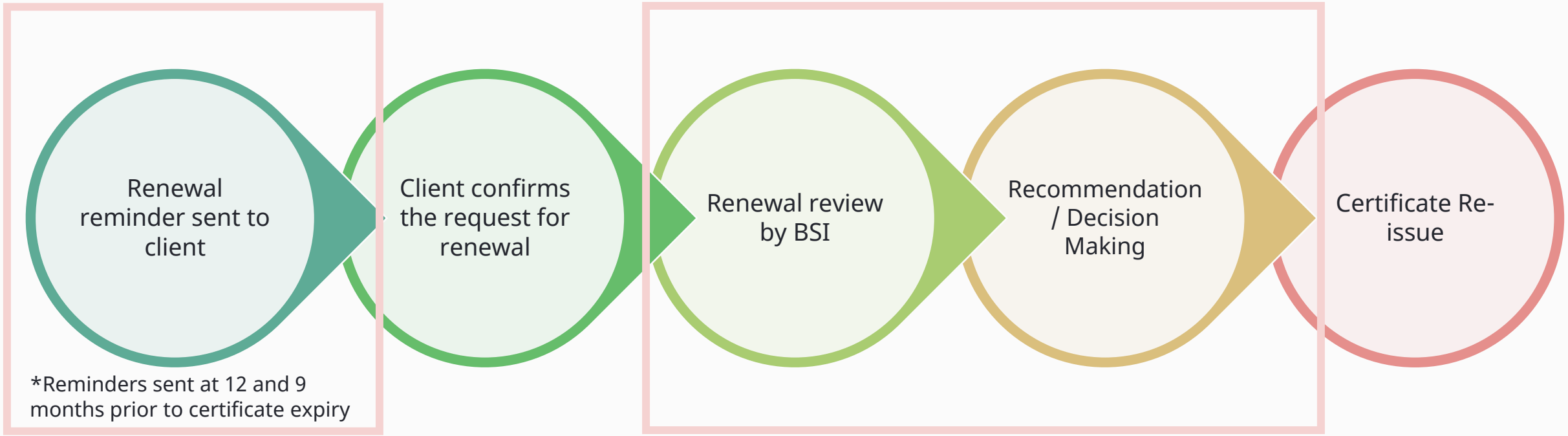
# The BSI Process

# Process Overview

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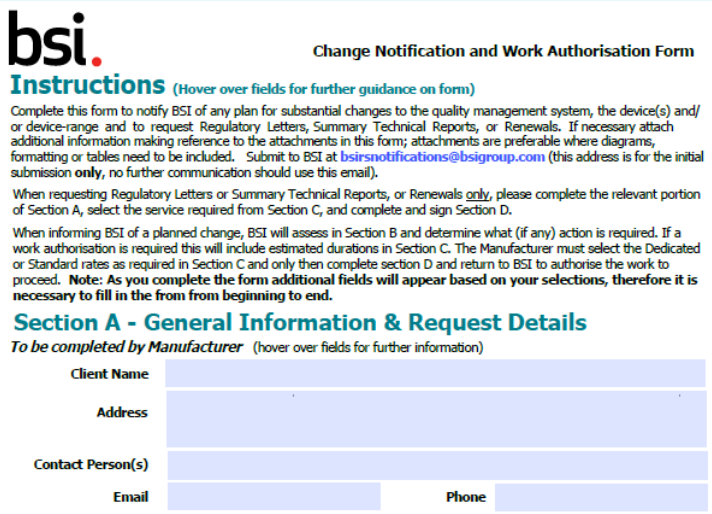
# Reminders

- 12 months
- 9 months – Renewal submissions received after this will be moved to dedicated
- Changes
- Consultations

# Forms being sent

As part of the renewal reminder a set of forms will be sent which need to be completed.

## MDF4900



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**Change Notification and Work Authorisation Form**

**Instructions** (Hover over fields for further guidance on form)

Complete this form to notify BSI of any plan for substantial changes to the quality management system, the device(s) and/ or device-range and to request Regulatory Letters, Summary Technical Reports, or Renewals. If necessary attach additional information making reference to the attachments in this form; attachments are preferable where diagrams, formatting or tables need to be included. Submit to BSI at bsirsnotifications@bsigroup.com (this address is for the initial submission **only**, no further communication should use this email).

When requesting Regulatory Letters or Summary Technical Reports, or Renewals only, please complete the relevant portion of Section A, select the service required from Section C, and complete and sign Section D.

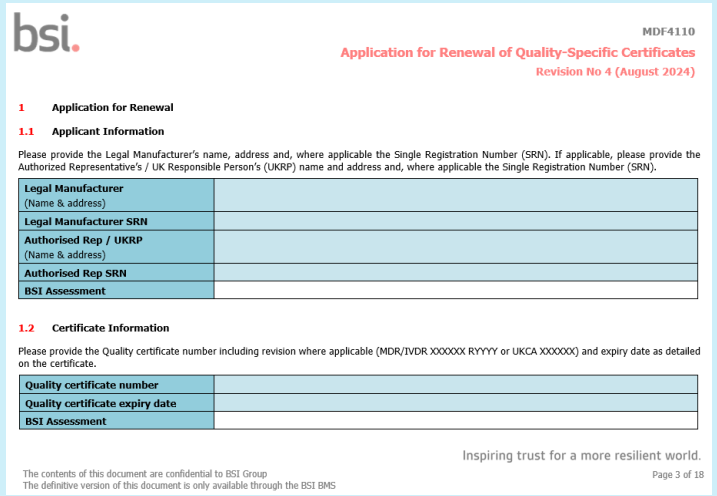
When informing BSI of a planned change, BSI will assess in Section B and determine what (if any) action is required. If a work authorisation is required this will include estimated durations in Section C. The Manufacturer must select the Dedicated or Standard rates as required in Section C and only then complete section D and return to BSI to authorise the work to proceed. **Note: As you complete the form additional fields will appear based on your selections, therefore it is necessary to fill in the from from beginning to end.**

**Section A - General Information & Request Details**

*To be completed by Manufacturer* (hover over fields for further information)

| | |
|---|---|
| Client Name | |
| Address | |
| Contact Person(s) | |
| Email | Phone |

## MDF4110 Quality Certificates



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MDF4110

Application for Renewal of Quality-Specific Certificates

Revision No 4 (August 2024)

**1 Application for Renewal**

**1.1 Applicant Information**

Please provide the Legal Manufacturer's name, address and, where applicable the Single Registration Number (SRN). If applicable, please provide the Authorized Representative's / UK Responsible Person's (UKRP) name and address and, where applicable the Single Registration Number (SRN).

| | |
|---|---|
| **Legal Manufacturer** (Name & address) | |
| **Legal Manufacturer SRN** | |
| **Authorised Rep / UKRP** (Name & address) | |
| **Authorised Rep SRN** | |
| **BSI Assessment** | |

**1.2 Certificate Information**

Please provide the Quality certificate number including revision where applicable (MDR/IVDR XXXXXX RYYYY or UKCA XXXXXX) and expiry date as detailed on the certificate.

| | |
|---|---|
| **Quality certificate number** | |
| **Quality certificate expiry date** | |
| **BSI Assessment** | |

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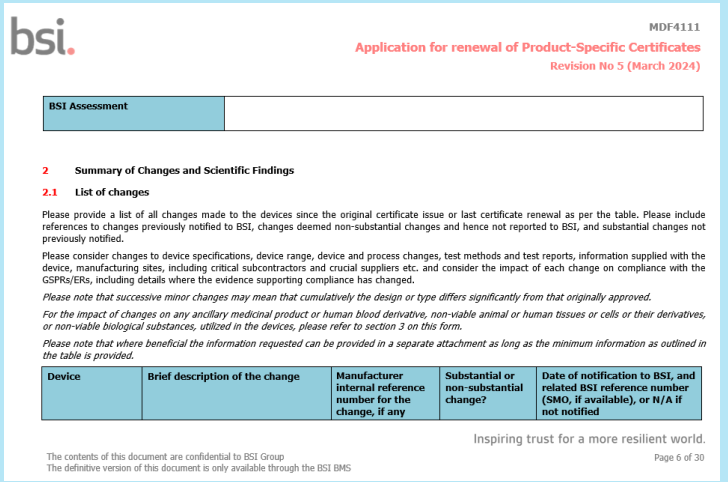
## MDF4111 Product Certificates



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MDF4111

Application for renewal of Product-Specific Certificates

Revision No 5 (March 2024)

| | |
|---|---|
| **BSI Assessment** | |

**2 Summary of Changes and Scientific Findings**

**2.1 List of changes**

Please provide a list of all changes made to the devices since the original certificate issue or last certificate renewal as per the table. Please include references to changes previously notified to BSI, changes deemed non-substantial changes and hence not reported to BSI, and substantial changes not previously notified.

Please consider changes to device specifications, device range, device and process changes, test methods and test reports, information supplied with the device, manufacturing sites, including critical subcontractors and crucial suppliers etc. and consider the impact of each change on compliance with the GSPRs/ERs, including details where the evidence supporting compliance has changed.

*Please note that successive minor changes may mean that cumulatively the design or type differs significantly from that originally approved.*

*For the impact of changes on any ancillary medicinal product or human blood derivative, non-viable animal or human tissues or cells or their derivatives, or non-viable biological substances, utilized in the devices, please refer to section 3 on this form.*

*Please note that where beneficial the information requested can be provided in a separate attachment as long as the minimum information as outlined in the table is provided.*

| Device | Brief description of the change | Manufacturer internal reference number for the change, if any | Substantial or non-substantial change? | Date of notification to BSI, and related BSI reference number (SMO, if available), or N/A if not notified |
|---|---|---|---|---|

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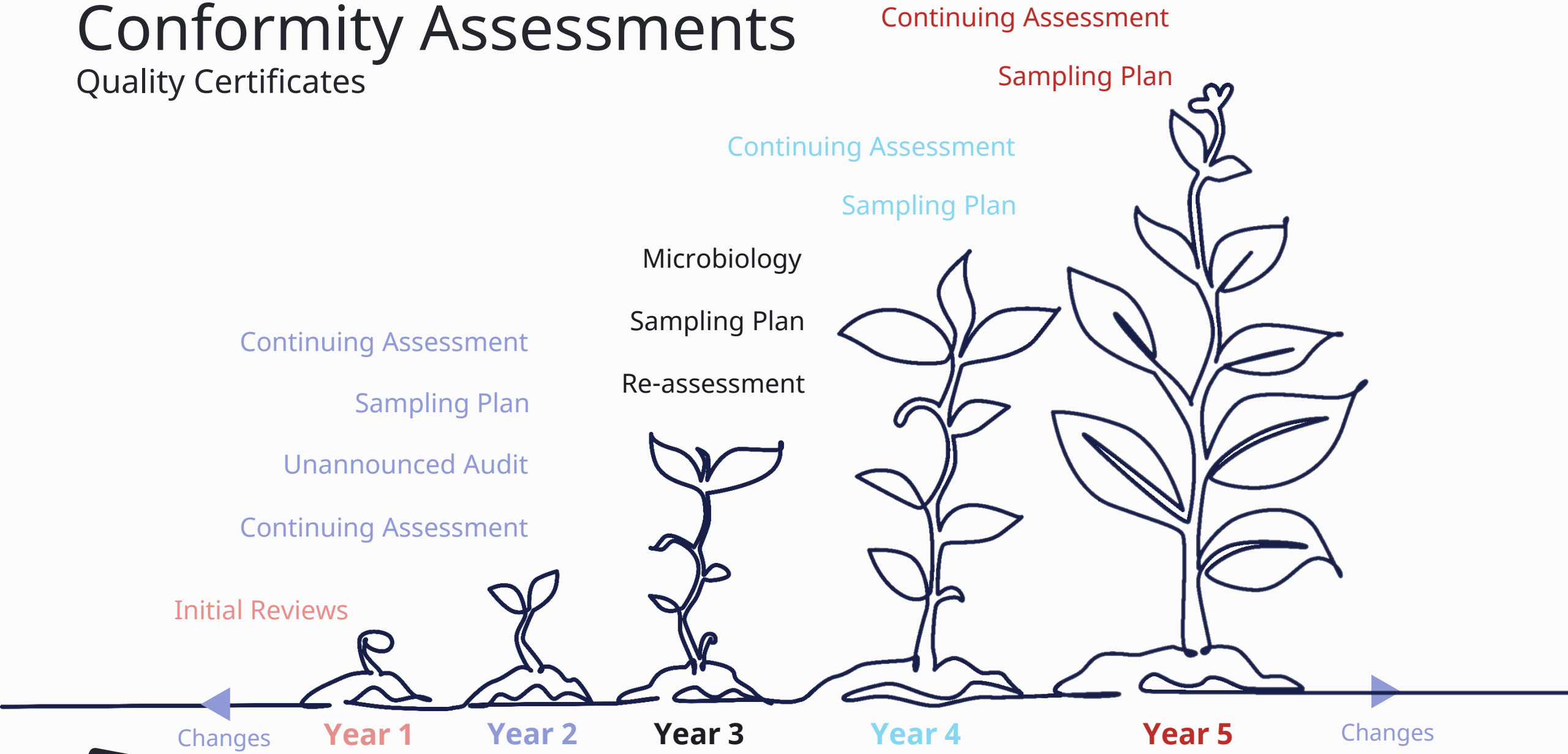
# Quality Certificates

# Conformity Assessments

## Quality Certificates




* As per sampling plan: TD review, PSUR + SS(C)P, Post Market

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# What needs to be reviewed?

Information to be provided by the manufacturer on MDF4110 and reviewed as part of the renewal review.

## Certificate Scope

- Legal Manufacturer & Authorised Rep / UKRP Details
- Device Schedule
- Critical Subcontractors & Crucial Suppliers

## For certain devices

- List of Modifications
- SS(C)Ps
- PSURs

## PMS

- Vigilance
- FSCAs

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# What needs to be reviewed? cont.

Information from BSI systems that is reviewed as part of the renewal review.

## Audit cycle

- QMS audits
- UAVs
- Microbiology audits

## TD Sampling

- Sample Details
- Audit Findings

## Summary of Renewal

- Outstanding Issues
- Certificate Information
- Upcoming certification cycle

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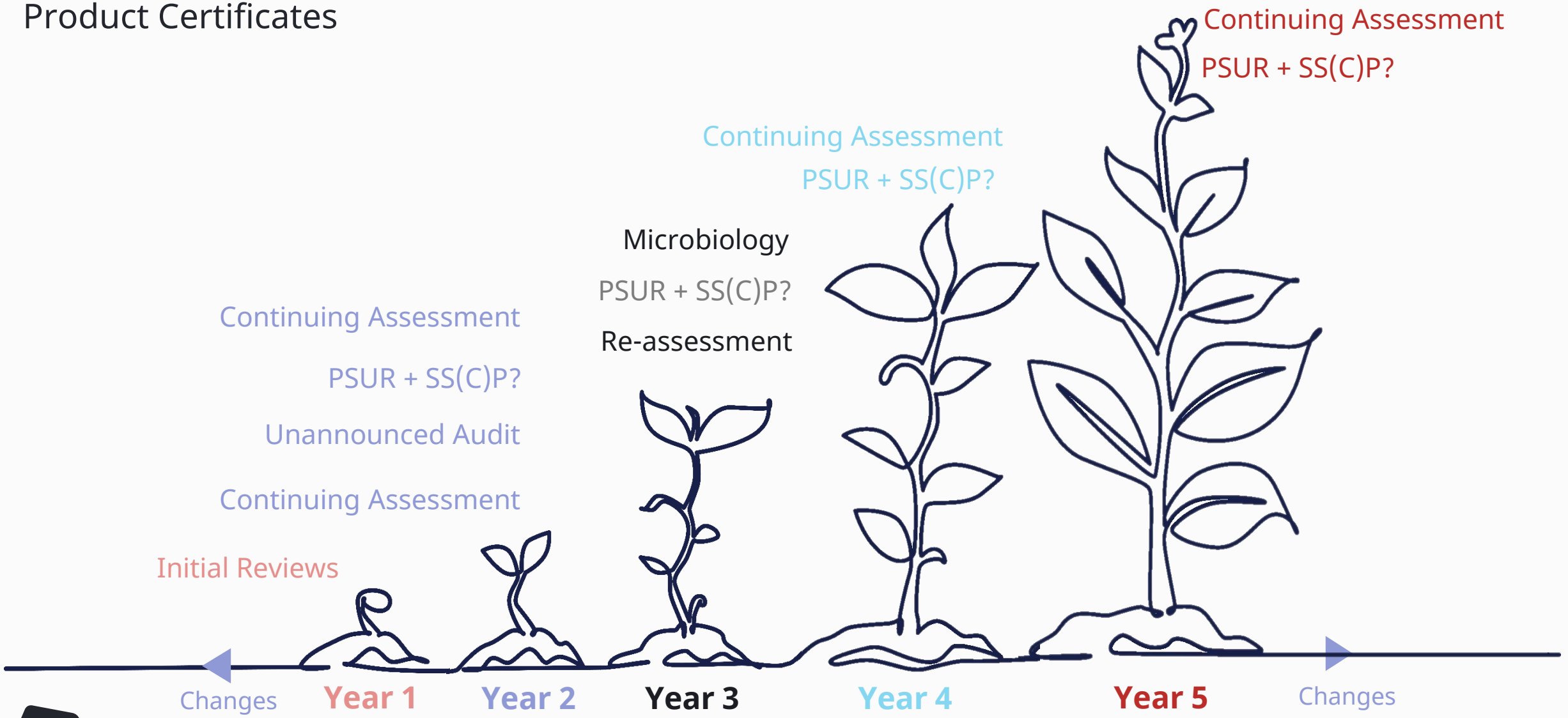
# Product Certificates

# Conformity Assessments

## Product Certificates

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# What needs to be reviewed?

Information to be provided by the manufacturer on MDF4111 and reviewed during the renewal review.

## Certificate Scope

- Legal Manufacturer & Authorised Rep / UKRP Details
- Device Schedule
- Critical Subcontractors & Crucial Suppliers

## Summary of changes and scientific findings

- What has changed?
- PMS
- Risk Management
- Proof of compliance
- Clinical/Performance Evaluation
- Regulations & Standards
- Changes in medical, scientific and technical knowledge

## Additional info for certain devices

1. IVD devices
2. Devices containing an ancillary medicinal product or human blood derivative
3. Devices utilizing non-viable animal tissue or cells or their derivatives
4. Devices utilizing non-viable human tissue or cells or their derivatives
5. Devices utilizing non-viable biological substances

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# Changes

(a) all changes to the originally approved device, including changes not yet notified,

## Guidance on Changes

- Section 4.9 of MDR Annex VII
- MDCG 2020-3
- NBOG 2014-3 for Medical Devices

## Focus of the Review

- Confirm substantial changes have been assessed by BSI.
- Confirm justifications for non-substantial changes.
- Not yet implemented changes will be reviewed separately.
- Implemented substantial changes not yet assessed by BSI will be reviewed separately. If safety and/or performance concerns the change review will need to be completed before the renewal can go ahead.

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# Post-Market Surveillance

(b) experience gained from post-market surveillance,

## UKCA Certificates

- PMS data is reviewed as part of MDF4111 (e) experience from reviews of the clinical evaluation

## MDR/IVDR Certificates

Periodic Safety Update Report – PSUR

- MDR - PSUR submissions and evaluations confirmed.
- IVDR Class C / Class B - PSUR / PMS report evaluated / reviewed.

Summary of Safety (and Clinical) Performance – SS(C)P

- MDR / IVDR - SS(C)P revalidated for any updates, and uploaded to EUDAMED.

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# Risk Management

## (c) experience from risk management

- Any updated occurrence rates due to feedback from the post-market surveillance data?
- Any new risks identified and have these been incorporated in the risk management and mitigated?
- Any updates identified in the risk management that would lead to an update of the IFU?
- Sufficient evidence available to demonstrate the risks still reduced as far as possible, and the benefit-risk ratio is still favorable in light of current state of the art?

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# Compliance

Review of evidence of compliance with GSPRs / ERs, updated regulatory requirements, standards etc.

## GSPR / ER Checklist

(d) experience from updating the proof of compliance with the general safety and performance requirements set out in Annex I,

## Regulatory Requirements

(f) changes to the requirements, to components of the device or to the scientific or regulatory environment,

## Standards

(g) changes to applied or new harmonized standards, CS or equivalent documents,

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# Clinical/ Performance Evaluation & State of the Art

(e) experience from reviews of the clinical evaluation, including the results of any clinical investigations and PMCF

- Clinical data collected from PMS/PMCF activities, changes to State of the Art and changes in Benefit-Risk.

(h) changes in medical, scientific and technical knowledge, such as:

- new treatments,
- **changes in test methods,**
- **new scientific findings on materials and components, including findings on their biocompatibility,**
- experience from studies on comparable devices,
- data from registers and registries,
- experience from clinical investigations with comparable devices.

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# Clinical Evaluations

Preparing your clinical evaluation documents for renewal.


# Key Focus Points of Clinical Evaluation at Recertification .

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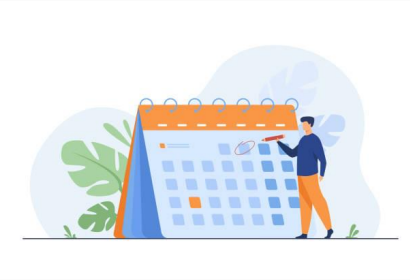
# Product Certificates

Devices on QMS Certificates will continue to be sampled throughout the certificate cycle. There will be no assessment of the clinical evaluation at recertification for these devices.

Devices on Product Certificates will be subject to a clinical evaluation by the notified body at recertification.

## The Notified and Approved Body clinical evaluation reviewers will focus on the following points at recertification:

1. The clinical reviewer will focus on changes to the state of the art in relation to the intended purpose to ensure that any changes have been identified by the manufacturer.

2. The clinical reviewer will focus on the clinical data gathered during the certificate period only and ensure that the clinical data continues to achieve a favourable benefit/risk assessment.

3. The clinical reviewer will focus on updates to your documentation including the Post Market Clinical Follow-up (PMCF) Plan and Summary of Safety and Clinical Performance (SSCP).

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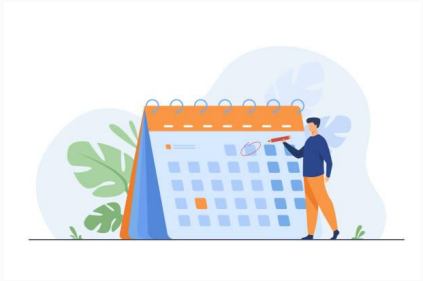

# State of the Art (SoTA)

- Recertification provides the opportunity to consider state of the art to ensure that the device is aligned to alternative diagnostics or therapies.
- The recertification process will look to ensure that your device continues to meet State of the art.
- Whilst it is unlikely that State of the art has changed significantly over 5 years for most devices, consideration should be given to changes in clinical practice.

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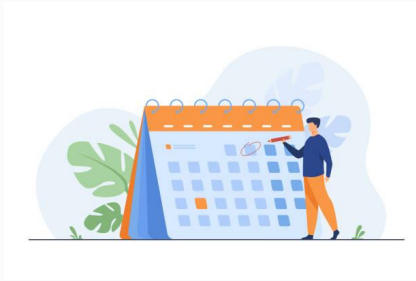

- Any changes in State of the Art will impact the clinical evaluation.
- State of the art changes may be identified through clinical literature, medical society guidance or national body guidelines.
- The biggest impact from SoTA changes will be to your overall safety and performance objectives.
- The manufacturer will be required to consider these changes in the context of their clinical data to justify that the device is indeed State of the Art.


# State of the Art (SoTA)

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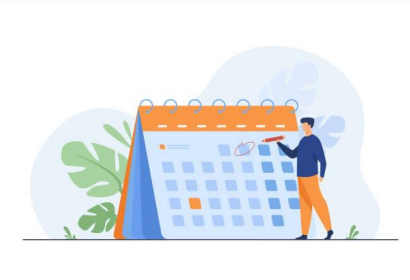


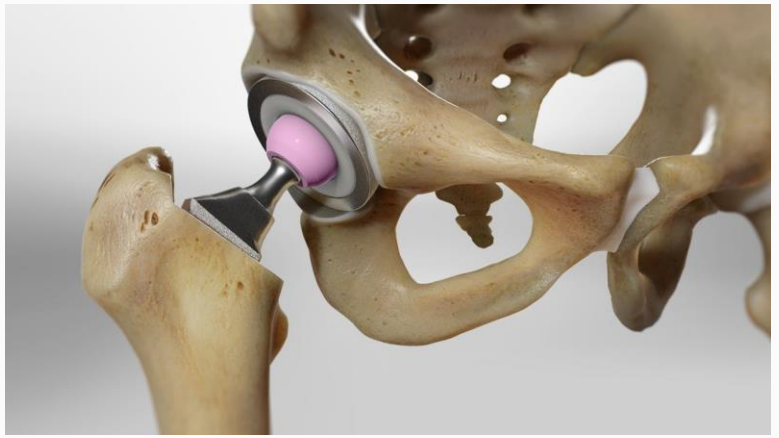
# State of the Art (SoTA)

Let us take an example of a Hip Implant.

2019- 90% Survivorship at 10 years was an acceptable level.

**2024 – 95% Survivorship at 10 years is now the new acceptable level.**

Manufacturers are looking to National Registry Data to verify that they are indeed meeting this new agreed objective.



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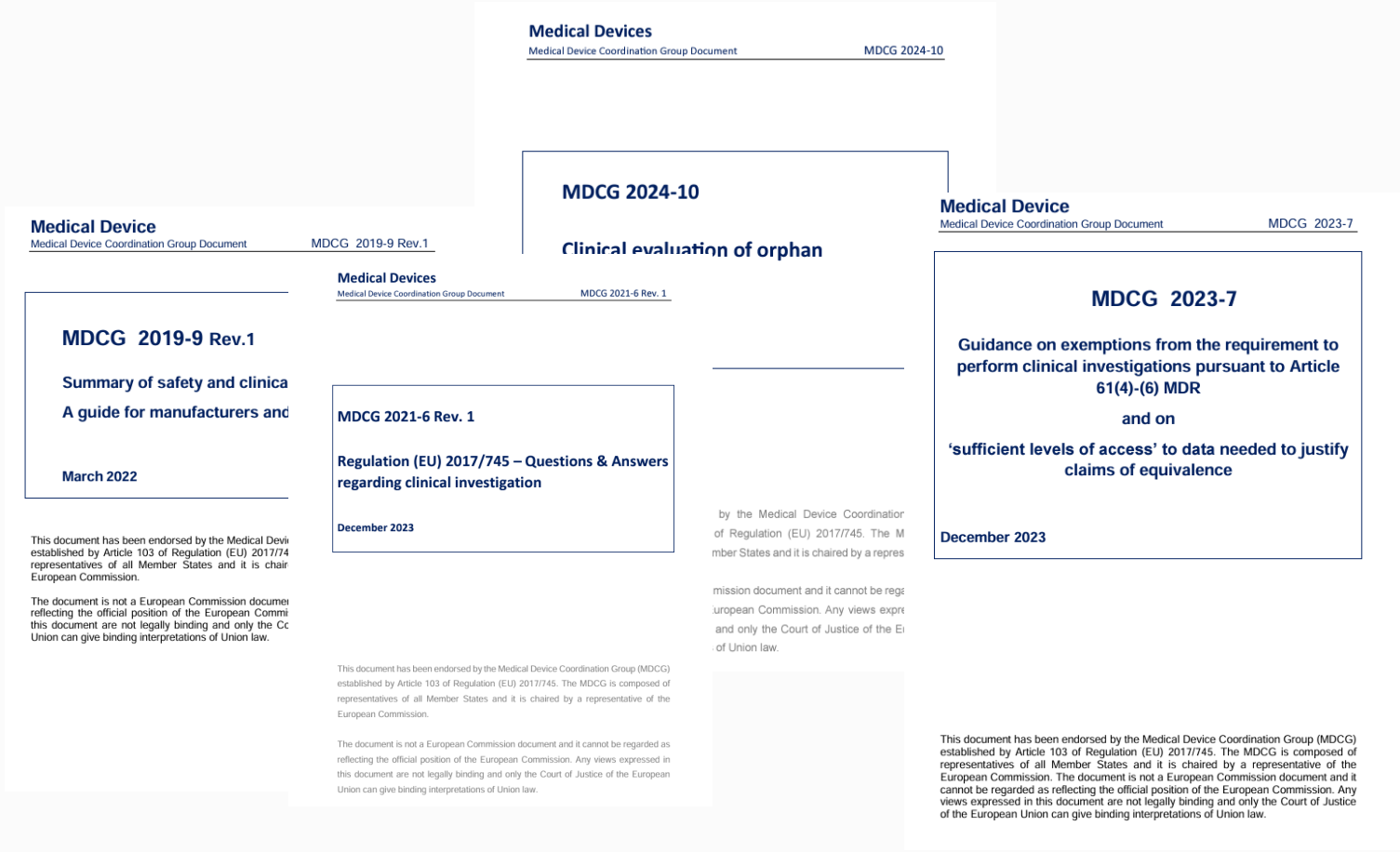
## Clinical investigation and evaluation

| Reference | Title | Publication |
|---|---|---|
| MDCG 2024-10 | Clinical evaluation of orphan medical devices | June 2024 |
| MDCG 2024-5<br>MDCG 2024-5 Appendix A | Guidance on the Investigator's Brochure content<br>Appendix A of the MDCG 2024-5 | April2024<br>April2024 |
| MDCG 2024-3<br>MDCG 2024-3 Appendix A | Guidance on content of the Clinical Investigation Plan for clinical investigations of medical devices<br>Clinical Investigation Plan Synopsis Template | March 2024<br>March 2024 |
| MDCG 2023-7 | Guidance on exemptions from the requirement to perform clinical investigations pursuant to Article 61(4)-(6) MDR and on sufficient levels of access' to data needed to justify claims of equivalence | December 2023 |
| 2023/C 163/06 | Commission Guidance on the content and structure of the summary of the clinical investigation report | May 2023 |
| MDCG 2021-28 | **Substantial modification** of clinical investigation under Medical Device Regulation | December 2021 |
| MDCG 2021-20 | Instructions for **generating CIV-ID** for MDR Clinical Investigations | July 2021 |
| MDCG 2021-8 | Clinical investigation **application/notification documents** | May 2021 |
| MDCG 2021-6 - rev.1 | Regulation (EU) 2017/745 – **Questions & Answers** regarding **clinical investigation** | December 2023 |
| MDCG 2020-13 - Word version | **Clinical evaluation assessment report template** | July 2020 |
| MDCG 2020-10/1 rev.1<br>MDCG 2020-10/2 rev. 1 | Guidance on **safety reporting** in clinical investigations<br>Appendix: Clinical investigation summary safety report form | October 2022<br>October 2022 |
| MDCG 2020-8 | Guidance on **PMCF evaluation report** template | April 2020 |
| MDCG 2020-7 | Guidance on **PMCF plan** template | April 2020 |
| MDCG 2020-6 | Guidance on sufficient **clinical evidence for legacy devices**<br>Background note on the relationship between MDCG 2020-6 and MEDDEV 2.7/1 rev.4 on clinical evaluation | April 2020 |
| MDCG 2020-5 | Guidance on **clinical evaluation – Equivalence** | April 2020 |
| MDCG 2019-9 - rev.1 | **Summary of safety and clinical performance** | March 2022 |

12 MDCG Clinical Investigations and Evaluation (CIE) guidance have been issued or Revised since the Date of Application. It is important manufacturers consider updates to MDCG guidance as part of their updates to the clinical evaluation.




[Link to EU Commission for MDCG Guidance]

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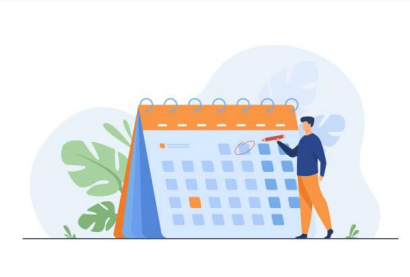

# Documentation

- When submitting your Clinical Evaluation Report, it is important to ensure that the report is up to date and has been updated according to the frequency defined by your QMS procedures.

- **TOP TIP:** Providing a redlined version of your CER to the reviewer, showing **all** updates made since last review ill help speed up your assessment, as the reviewer is focusing on changes and new data.

- The CER should contain updated information from your PMS and PMCF, and this data should be considered in the context of your overall clinical evaluation.


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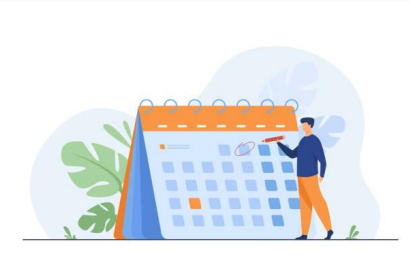
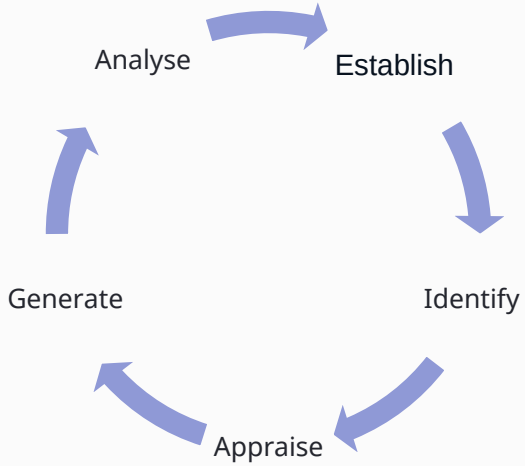


# Point of Clarification

11. The clinical evaluation and its documentation shall be updated throughout the life cycle of the device concerned with clinical data obtained from the implementation of the manufacturer's PMCF plan in accordance with Part B of Annex XIV and the post-market surveillance plan referred to in Article 84.

For class III devices and implantable devices, the PMCF evaluation report and, if indicated, the summary of safety and clinical performance referred to in Article 32 shall be updated at least annually with such data.




Whilst Article 61 (11) of the EU MDR regulation calls out an update to the PMCF evaluation report annually, this data **cannot** be considered in isolation of the overall clinical evaluation and the main findings of your PMCF evaluation report need to be considered in your overall benefit-risk as part of the Clinical Evaluation Report.

This aligns to the Clinical Evaluation process described in Annex XVI.

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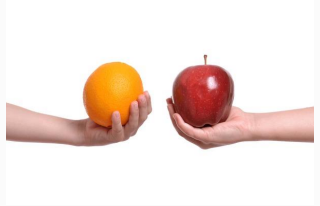

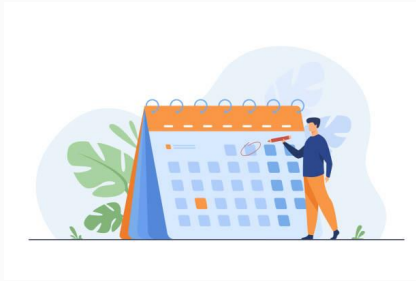

# Experience gained with the device.

- As part of the recertification process, the reviewer will be looking closely at the PMS and PMCF data that has been obtained during the certificate cycle ensuring that the manufacturer has followed their PMCF plan.
- The focus of the assessment will be on any new data gathered and assessing the validity of this data in the context of the overall clinical evaluation.
- The reviewer will be looking to ensure that the data continues to align to the State of the art and consider any changes to the overall benefit-risk of the device.

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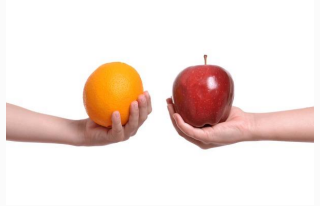

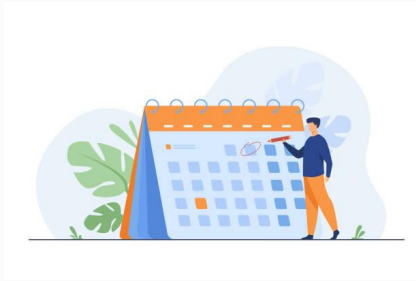

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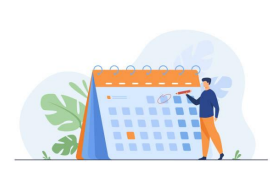

# Equivalence at Recertification

- The purpose of claiming equivalence is to allow the data from another device's data to enter the evaluation, and for the manufacturer to truly prove that the device is equivalent through PMCF.
- It is not acceptable to continue to rely on equivalence on recertification without any data on your own device.
- The reviewer will be looking to ensure that the manufacturer has collected their own data and followed the agreed PMCF plan.
- Devices at recertification that rely solely on equivalence , without any data on their own device, will **not** be accepted.

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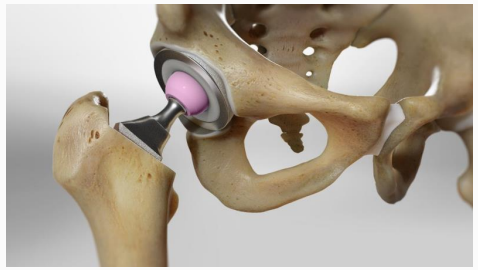
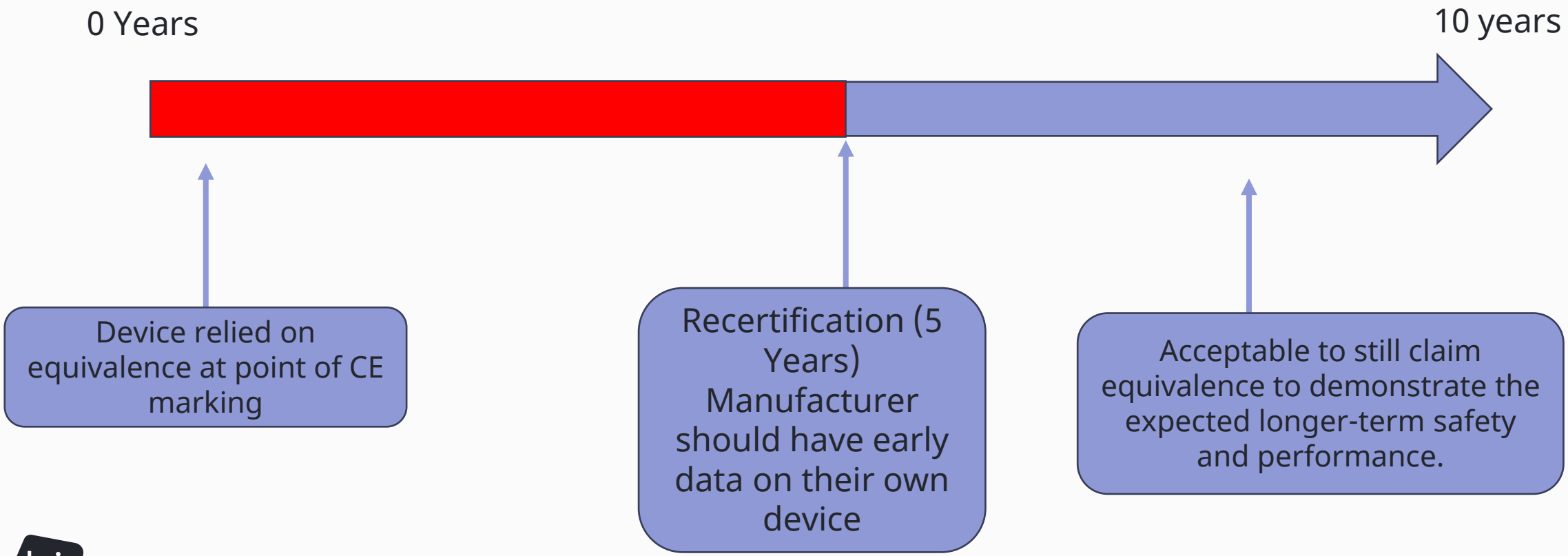
# Equivalence at Recertification



- Example Hip Implant that claimed Equivalence at CE Marking.
- The Hip Implant has a claimed lifetime of 10 Years

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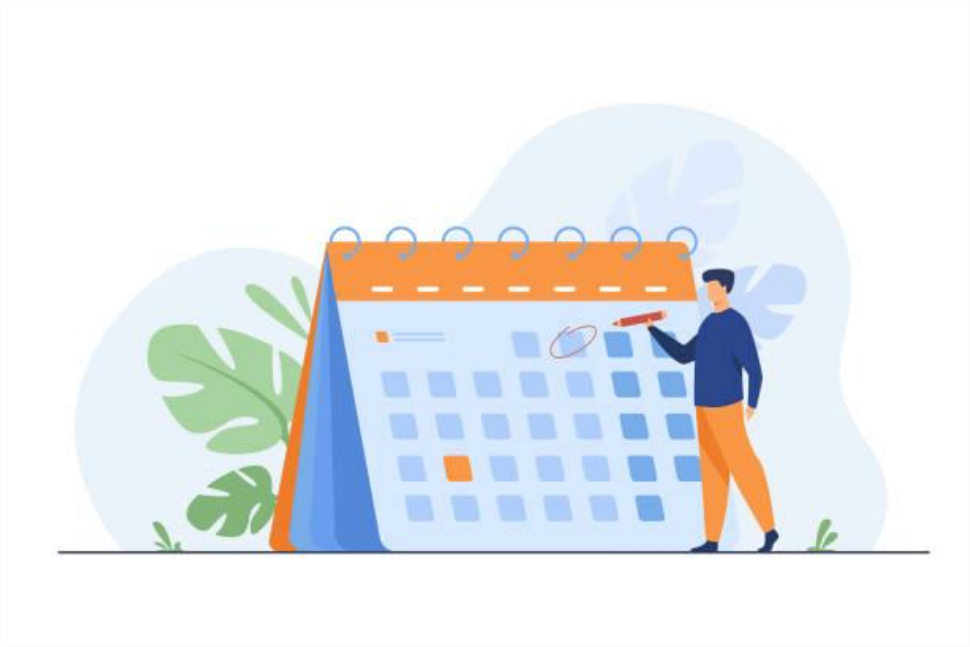
# PMCF Plan Updates



- The reviewer will consider and review updates to your PMS and PMCF Plan.
- Updates to your PMCF plan may include initiation of any new activities.
- Additional activities may be needed to address emergeing concerns.
- The reviewer will consider any justifications for specific PMCF activities. (Registries, PMCF Studies)
- There is an expectation that general PMCF activities will continue.

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# PMCF Studies through the lifecycle of a device.

PMCF Studies may be required at different stages of a device lifecycle.

Device Launch.


Identify emerging or clarify impact of newly identified risks.

Modifications to a device to ‘improve’ safety and performance

To help identify risks at a later stage of the device’s lifetime

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Devices may get to the market with clinical data that does not cover the lifetime of the device. In this situation, a PMCF study may need to look at longer term data. The PMCF study here may be asking questions to include:

- Are there residual risks occurring later in the lifetime of the device?
- The difference in the device performance at the later stage of lifetime compared to time of implant?
- Does the risk to the patient change with age or change in severity of disease?

**Example of a PMCF study Initiated because of longer Term Safety and Performance risks**

- Data from scientific communities suggesting a link between certain types of breast implant design and ALCL (Anaplastic Large Cell Lymphoma)
- Need to evidence the risk with the specific type of implants.
- PMCF Study (Registry based Study) Initiated on 10-year-old Implants.

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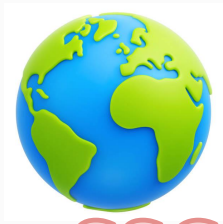


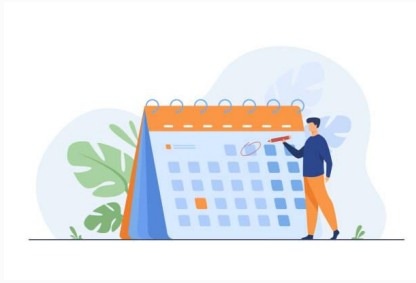

# SSCP Updates

**Medical Device**
Medical Device Coordination Group Document MDCG 2019-9 Rev.1

**MDCG 2019-9 Rev.1**

**Summary of safety and clinical performance**
**A guide for manufacturers and notified bodies**

**March 2022**

- For devices that are on a product certificate you will need to provide an **updated** SSCP to the notified body.
- Even if your SSCP has not been updated since last certificate issue, you will still need to provide an updated SSCP.

**Validation of SSCP at certificate renewal**

With each certificate renewal application, the manufacturer should:

- For class III devices and class IIb implantable devices, other than sutures and staples etc.[42], submit a draft SSCP which has been updated within the previous 12 months, regardless of whether there are new data or conclusions.
- For class IIa implantable and IIb implantable devices, such as sutures and staples etc.[43], confirm that the SSCP in Eudamed is in alignment with the current version of the TD, or provide an updated SSCP where required.

At certificate renewal, the same principles should apply for the validation of the SSCP documents as at the initial certification.

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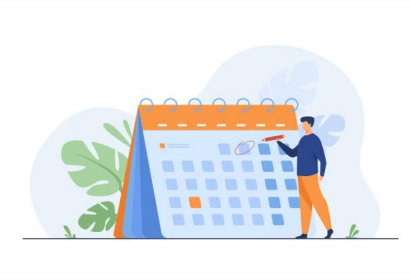

## The Notified and Approved Body clinical evaluation reviewers will focus on the following points at recertification:

1. The clinical reviewer will focus on changes to the state of the art in relation to the intended purpose to ensure that any changes have been identified by the manufacturer.

2. The clinical reviewer will focus on the clinical data gathered during the certificate period only and ensure that the clinical data continues to achieve a favourable benefit/risk assessment.

3. The clinical reviewer will focus on updates to your documentation including the Post Market Clinical Follow-up (PMCF) Plan and Summary of Safety and Clinical Performance (SSCP).

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# What to look out for?

# Key things to look out for

1. Be PRO-ACTIVE
2. CHECK what certificates you have that are expiring over the next 12-15 months
3. Be AWARE of any NCs, Follow-Up Actions, Change Notifications, Change in Full-Time Employee Nos. (this can affect audit durations) etc.
4. AVOID the pressure of dealing with an expired certificate that may have to be cancelled.

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# Questions?

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