Medical Product Certification

# 10 Steps to CE-Mark

certification process from the point of view of MDR Notified Body

Presentation | Vasily Kalakutskiy | 2024-10-11


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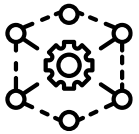
- Review 10 Steps to CE mark
- Focus on requirements for certification
- See what it takes from the first inquiry to the beginning of the audit
- Zoom in and out to understand certification process elements
- Useful links
- Q&A session

## STEP 1

Is your device a Medical Device (MD)?

- MDR Art. 2



## STEP 2

Classification & SRN

- MDR Ann. VIII
- MDR Art. 31 & Ann. VI
- SRN from Eudamed

## STEP 3

Implement a QMS

- MDR Art. 10
- EN ISO 13485 to meet key MDR requirements

## STEP 4

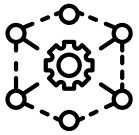
Prepare Technical Documentation (TD)

- MDR Ann. I (GSPR)
- MDR Ann. II (structure)

## STEP 5

Appoint an EU Authorized Rep

- Written agreement
- MDR Art. 11
- Registration in Eudamed



## STEP 6

Agreement with a Notified Body (NB)

- Class Is/m/rsi, IIa, IIb, III
- Notified scope: Nando database

## STEP 7

Get EU Certificate

- After successful NB Audit & TD Assessment

## STEP 8

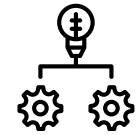
Register devices in Eudamed

- UDI to be assigned to all MD
- MDR Ann. VI parts B & C

## STEP 9

Sign the Declaration of Conformity (DoC)

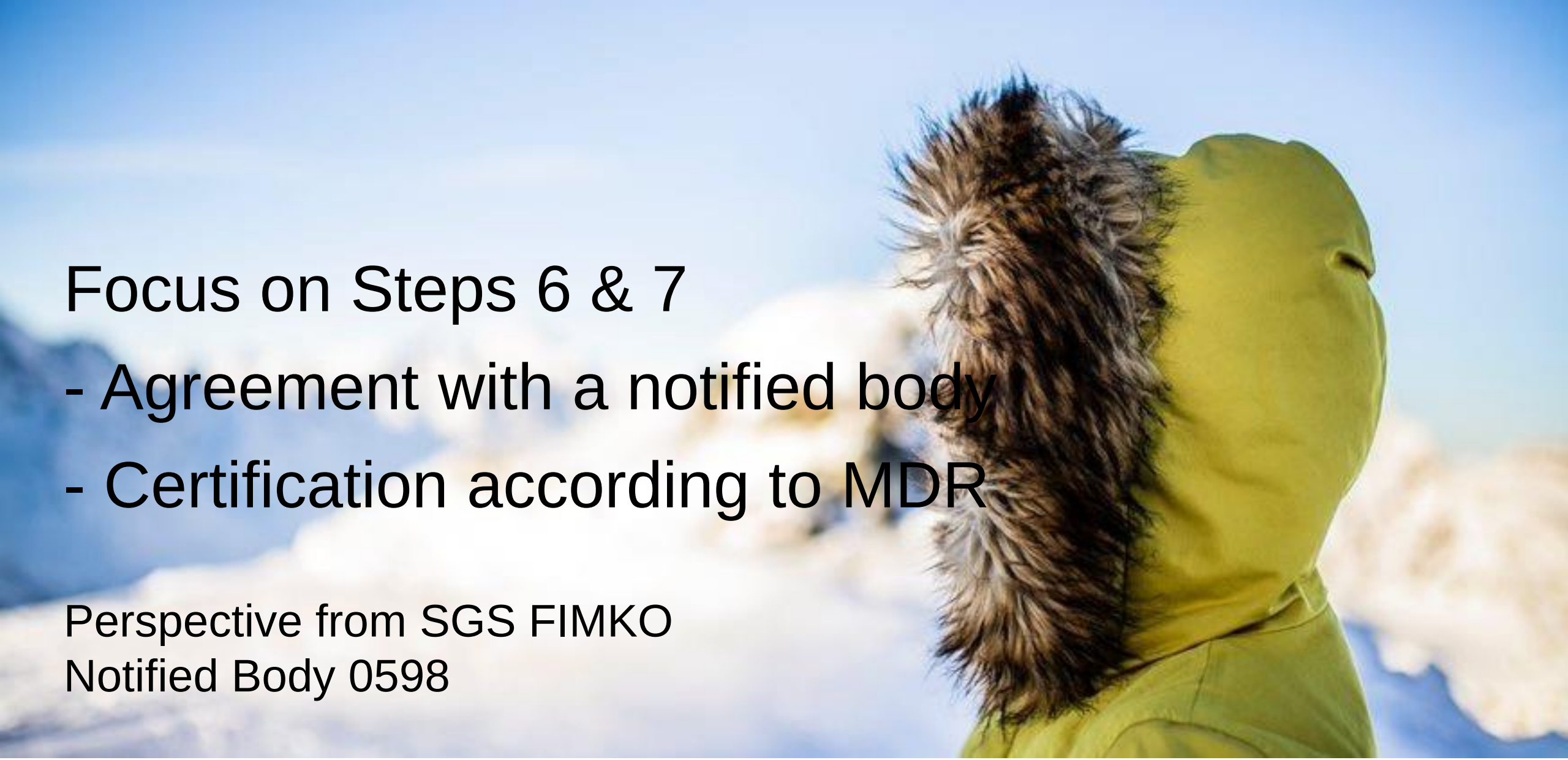
- MDR Ann. IV



## STEP 10

Affix the CE Mark

- Including NB number for class Is/m/rsi, IIa, IIb, III



# Focus on Steps 6 & 7

- Agreement with a notified body
- Certification according to MDR

Perspective from SGS FIMKO
Notified Body 0598

# Certification according to MDR requirements

- Notified body SGS Fimko Oy (CE0598) works under the notification from the competent authority of Finland (FIMEA)
- Local service provider for the certification services on behalf of SGS Fimko in Germany is SGS Germany GmbH
- Certificates that can be issued:
  - ISO13485 certificate with validity of 3 years
  - EU certificate according to MDR for maximum 5 years (depends upon the certification decision, shorter term certificates can be issued to collect additional clinical evidence etc)
- Surveillance frequency (12 months) and duration of visits are regulated by MDR.
- Unannounced audit at least once during the certification cycle (3-5 years), frequency can be increased if risk factors.
- Audits can be carried out in English, German, Spanish, Finnish and Swedish languages.
- TD is preferred to be in English, Finnish or Swedish languages.
- Low level documentation for manufacturing or R&D may remain in local language.

# Requirement to have an established QMS

- Manufacturer must have experience with QMS according to EN ISO13485:2016
  - Hold ISO13485 QMS certified by a recognized certification body

  **or**

  - Apply for ISO13485 certification to SGS FIMKO before applying for MDR services
- SGS Fimko will take over the existing ISO13485 certification and handle it together with MDR
- Certification according to MDR requirements is offered only after the manufacturer has achieved ISO13485 certification.
- ISO 13485 certification is not compulsory, but because MDR compliant QMS is compulsory, ISO 13485 certification may be a good starting point.

# From the first inquiry to project opening

**Customer inquiry**

Customer requests per e-mail and fills out 2 questionnaires and returns them back to SGS. We check if the product in application is in the scope of the notified body and make up a non-binding offer.

1-2 weeks

**Non-binding offer**

Customer agrees to the non-binding offer – including costs of the application review - and fills out a MDR agreement with 6 attachments. It is submitted to SGS together with top level QMS documents and draft version of TD

Timeline is up to customer

**Binding offer**

SGS performs the application review and based on the results, prepares binding offer and pre-books resources. Customer accepts the binding offer. MDR agreement is signed.

3-4 weeks

**Project opening**

As soon as the order is confirmed by customer and MDR agreement is signed, SGS confirms the schedule and audit activities may start.

# Offer elements

## Application review

Application review fee

## Initial certification (V1)

Stage 1 Audit

Preparation and reporting

TD assessment

Use of internal clinician

Stage 2 Audit

Preparation, reporting and final review

Annual certification fee

## Surveillance (V2)

Surveillance Audit

Preparation, reporting and final review

TDA sampling

Annual certification fee

## Surveillance (V3)

Surveillance Audit

Preparation, reporting and final review

TDA Sampling

Annual certification fee

## Re-certification (V1R)

Re-certification Audit

Preparation, reporting and final review

TDA Sampling

Annual certification fee

1 x Unannounced audit (2 auditors @1 day)

# Visits: what is done when

## Initial certification (V1)

Audit of Quality Management System Stage 1 and Stage 2 including early re-certification if ISO13485

Review of technical documentation

Review by clinician

Certification review

Issuing of ISO and MDR certificates. These 2 certificates will be handled together from V1 and on.

## Surveillance (V2)

MDR QMS Surveillance Audit

Technical Documentation surveillance

Review by clinician

## Surveillance (V3)

MDR QMS Surveillance Audit

Technical Documentation surveillance

Review by clinician

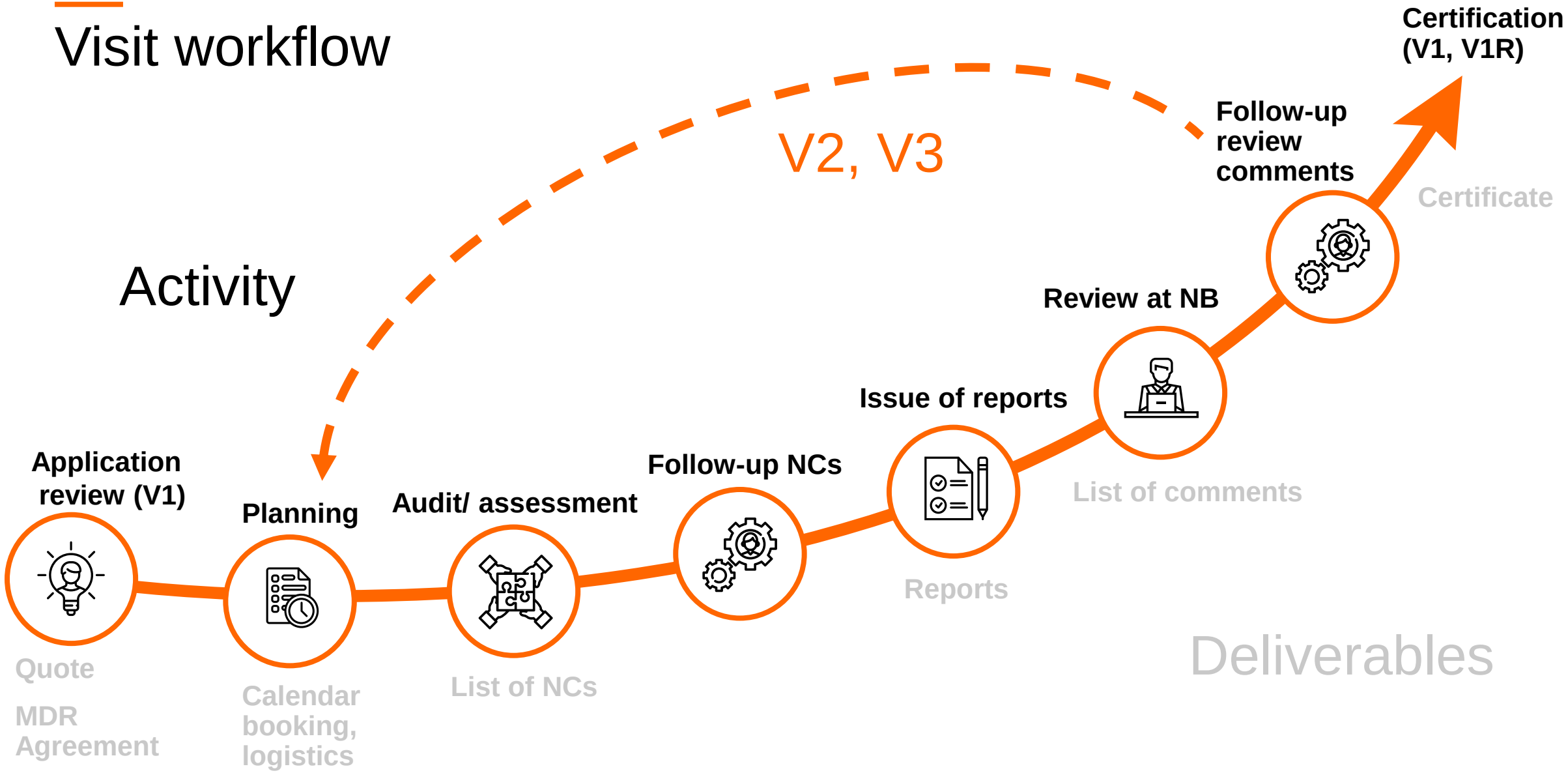
## Re-certification (V1R)

MDR QMS Re-Certification Audit

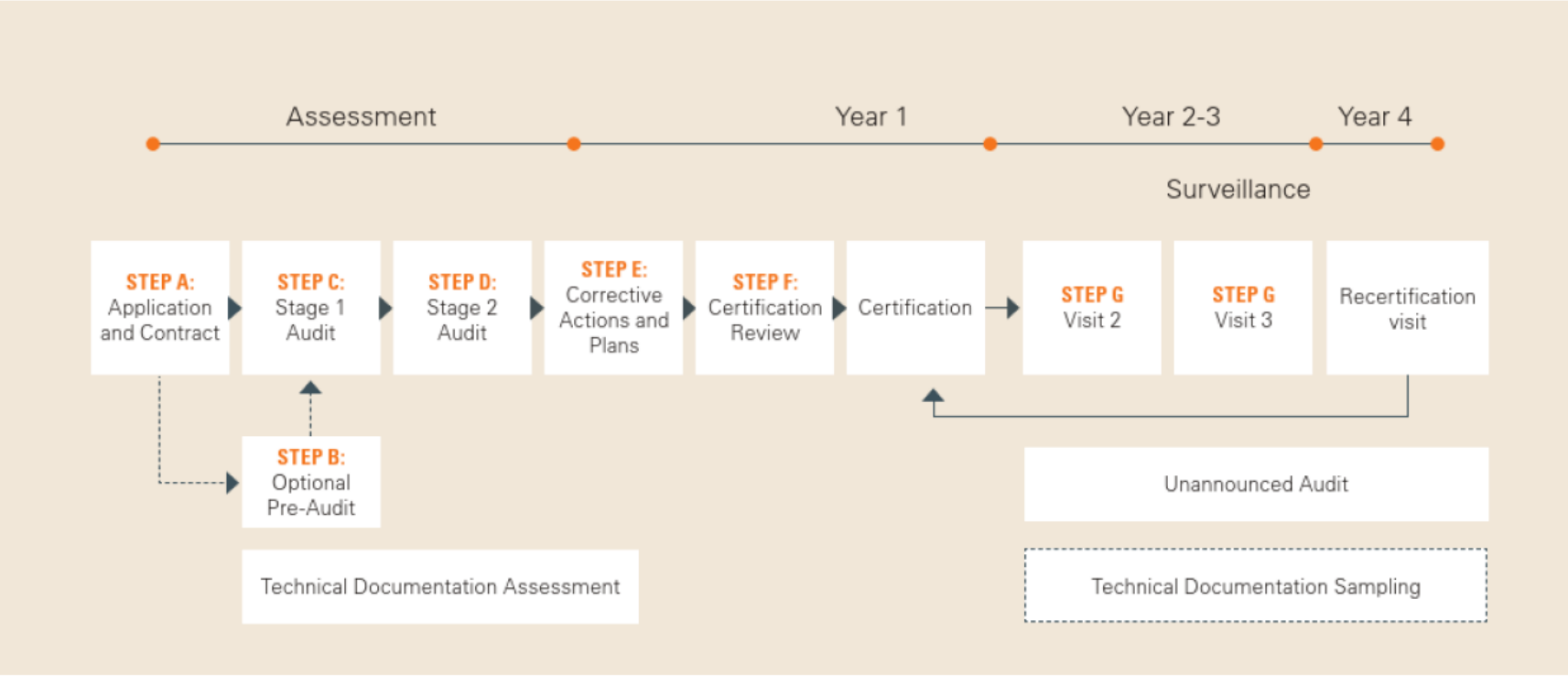
Technical Documentation surveillance

Re-issue / update of certificates

# Visit workflow



# Certification Process Overview (MDR)



# Useful links about SGS Fimko certification process

- For more details visit SGS Germany homepage:

https://www.sgs-cge.de/en/business-fields/medical-technology/ce-marking-of-medical-devices.html

- Certification process in English:

https://www.sgs-cge.de/images/pdf/FPMDREG1015_-_MDR_Your_Certification_Process_Explained_Ver_Iprint.pdf

- Standard fees and charges:

https://www.sgs.fi/-/media/local/finland/documents/technical-documents/technical-datasheets/nb-0598-standard-fees.pdf?la=en

- Scope of MDR certification:

https://webgate.ec.europa.eu/single-market-compliance-space/#/notified-bodies/notifications/323237?organizationVersion=18

# Contact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