Medical Product Certification

10 Steps to CE-Mark

Certification process from the point of view of MDR Notified Body

Presentation | Vasily Kalakutskiy | 2023

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10 Steps to CE Mark - Overview

STEP 1

Is your device a Medical Device (MD)?

- MDR Art. 2

STEP 2

Classification & SRN

- MDR Ann. VIII
- MDR Art. 31 & Ann. VI

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

STEP 6

Appoint a Notified Body (NB)

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

STEP 7

Get European EC Certificate

- After successful NB Audit & TD Assessment

STEP 8

Register in Eudamed

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

STEP 9

Prepare a 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

- Notified Body and CE Certification

Perspective from SGS FIMKO
Notified Body 0598

MDR CE certification service

- For medical device manufacturer with certified QMS according to ISO13485
- Notified body SGS Fimko (NB0598) working under the notification from competent authority Fimea
- Local service provider in Germany is SGS Germany GmbH
- ISO13485 certificate validity - 3 years
- MDR EC Certificate validity - 5 years
- Frequency (12 months) and duration of visits are regulated by law.
- Unannounced audit at least once during the certification cycle

From the first inquiry to project opening

Customer inquiry

Customer fills out 2 questionnaires and returns them to SGS.

If the product is in the scope of the notified body, a non-binding offer can be prepared by SGS Germany.

Non-binding offer

If the customer agrees to the estimation of the project, a certification agreement with 6 attachments must be filled out and sent to SGS.

1-2 weeks

Binding offer

Application Review & Application Fee

SGS Germany together with the notified body prepares the exact quotation and does preliminary booking of resources.

3-4 weeks

Project opening

As soon as the order is confirmed by customer, SGS books the resources and plans all audit activities.

MDR EC certification – quotation elements

Application review

Application review

Application fee

Initial certification (V1)

MDR QMS audit:

- Stage 1
- Stage 2

TD assessment

CD assessment

Annual certification fee

Surveillance (V2)

MDR QMS Surveillance Audit

TD Surveillance

CD Surveillance

Annual certification fee

Surveillance (V3)

MDR QMS Surveillance Audit

TD Surveillance

CD Surveillance

Annual certification fee

Re-certification (V1R)

MDR QMS Audit

TD Assessment

CD Assessment

Annual certification fee

MDR EC certification – visits: what is done when

Initial certification (V1)

Transfer of QMS to FIMKO

Audit of Quality Management System Stage 1 and Stage 2

Review of technical documentation

Review of clinical documentation

Certification review

Issue of ISO and MDR certificates

Surveillance (V2)

MDR QMS Surveillance Audit

Technical Documentation (TD) surveillance

Clinical Documentation (CD) surveillance

Surveillance (V3)

MDR QMS Surveillance Audit

Technical Documentation (TD) surveillance

Clinical Documentation (CD) surveillance

Re-certification (V1R)

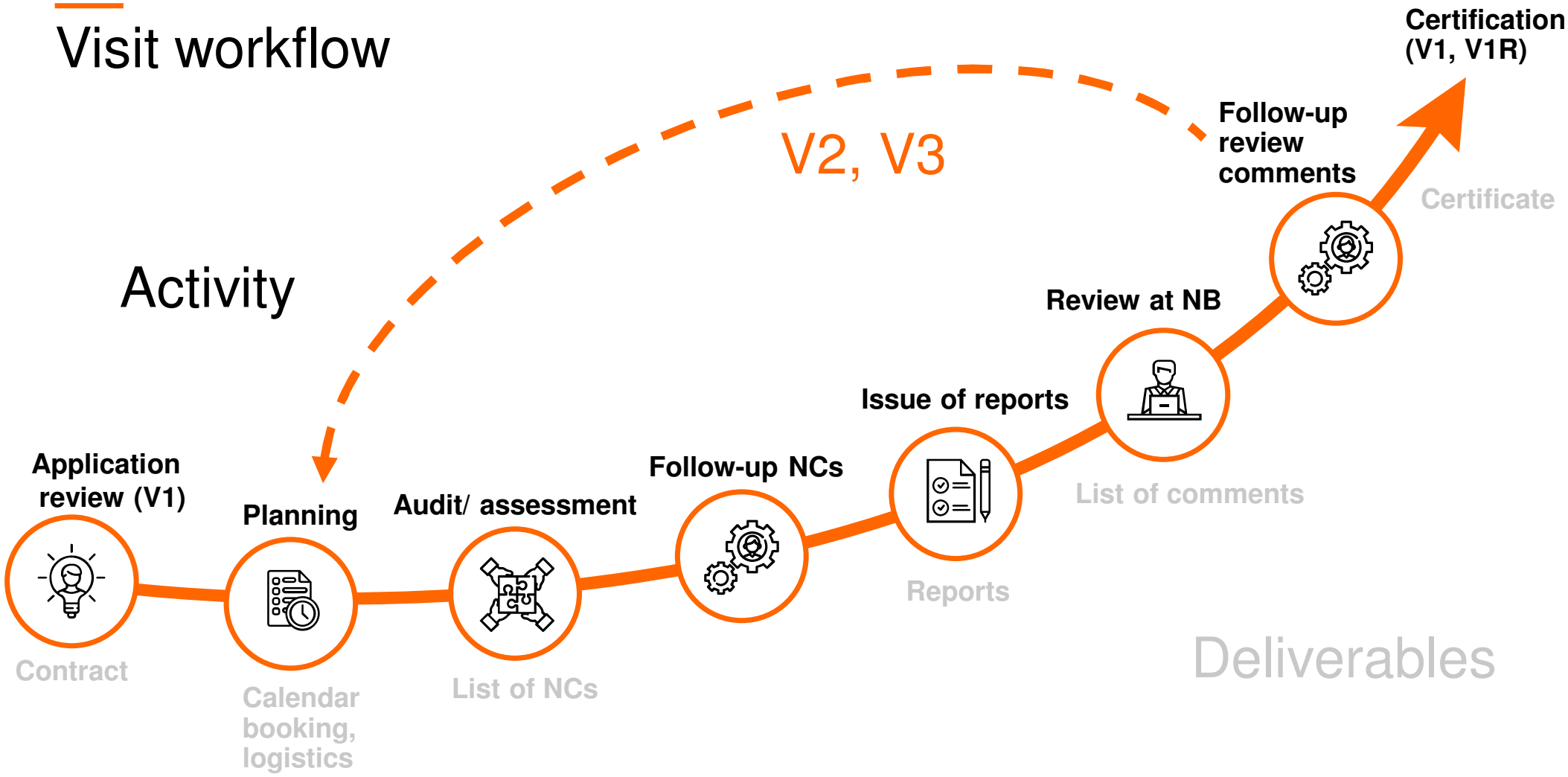
MDR QMS Re-Certification Audit

Technical Documentation (TD) assessment

Clinical Documentation (CD) assessment

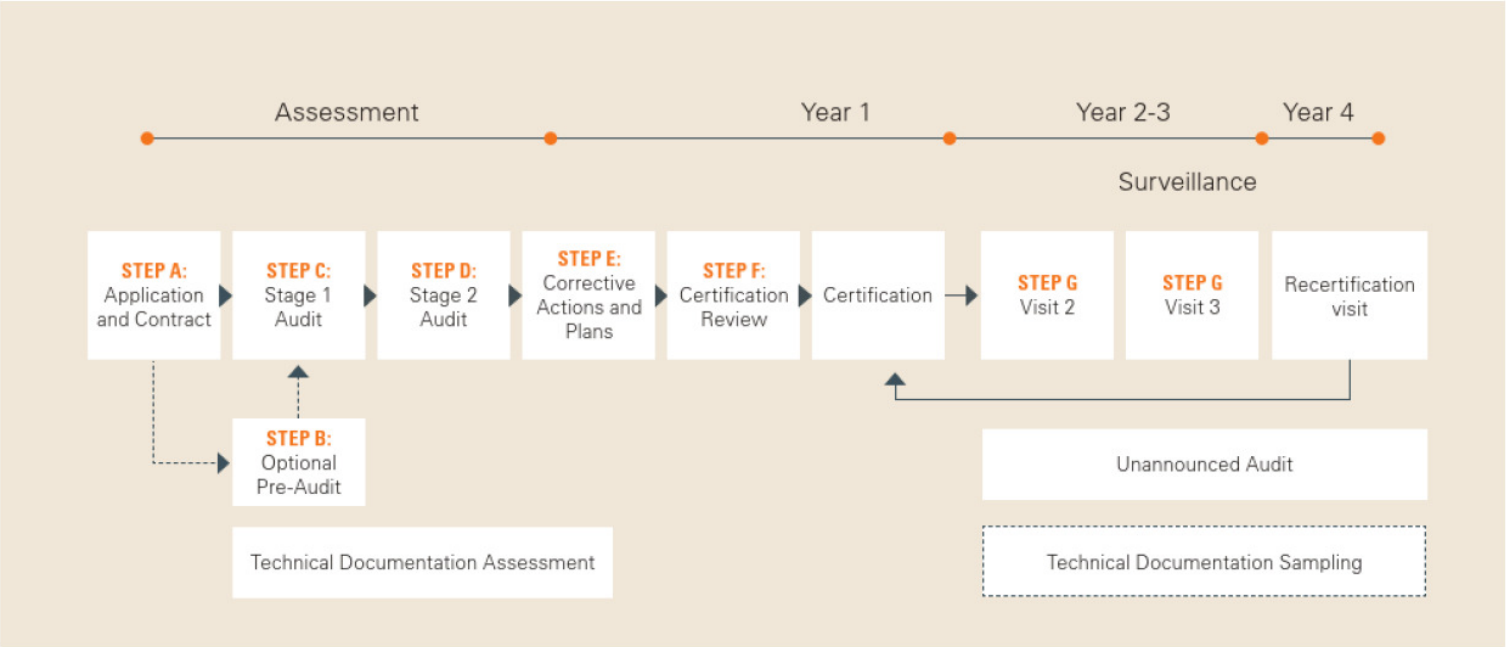
Re-issue / update of certificates

Visit workflow



MDR Certification Process

OVERVIEW OF OUR CERTIFICATION PROCESS



Useful links about SGS Fimko certification process

- For more details visit our new homepage in German:

https://www.sgs-cqe.de/de/service-portfolio/2017-06-02-5/eu-zertifizierung-medizinprodukte.html

- Certification process in English:

https://www.sgs-cqe.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-2022.pdf?la=en

- Scope of MDR certification:

https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=notification.pdf&dir_id=34&ntf_id=310591

Questions?

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Thank you!