National Standards Authority of Ireland
Údarás Um Chaighdeáin Náisiúnta na hÉireann

SCHEDULE 2

SPECIAL TERMS & CONDITIONS – Medical Devices

MEDICAL DEVICES QUALITY MANAGEMENT SYSTEMS AND MEDICAL DEVICE CERTIFICATION

1 INTRODUCTION

NSAI medical devices offers certification to the following conformity assessment schemes/standards -

- Non-regulatory EN ISO 13485:2016 / ISO 13485:2016
- ISO 9001:2015 in combination with EN ISO 13485:2016 / ISO 13485:2016
- EU Regulatory (MDR/IVDR/IVDD) EN ISO 13485:2016 quality management system audit and associated product technical file review
- Medical device single audit programme (MDSAP)

Definitions

MDR means Regulation (EU) 2017/745 on Medical Devices

IVDR means Regulation (EU) 2017/746 on In-Vitro Diagnostic Medical Devices

IVDD means Directive 98/79/EC on In-Vitro Diagnostic Medical Devices

MDSAP means the Medical Device Single Audit Program

Stages for Applications

- Application submitted to NSAI using the NSAI online form. NSAI reviews application.
- NSAI signed Quotation Letter is sent to applicant in conjunction with Schedule 1 - General Terms and Conditions, Schedule 2 - Special Terms and Conditions.
- Client agrees to the quotation, signs and returns Quotation Letter to NSAI.
- Contract in force between NSAI and Client for the initial application(s).
- Further applications may be submitted from time to time under the Contract – see Schedule 1 (General Terms & Conditions)

2 OUTLINE OF THE AUDIT PROCESS

Note: NSAI may carry out audits remotely, at its discretion.

2.1 Stage 1 audit assessment

- An audit plan will be provided by the NSAI lead auditor in advance of the audit
- In general, a portion of the assessment will occur onsite at the Client's location
- If applicable, open dated invitation letters for Visas are required to be provided by the Client to the audit team to allow visits to sites, suppliers and sub-contractor locations
- NSAI will review at least the following documentation; this list is not exhaustive and is subject to change
  - The scope of the quality management system
  - The quality management system documentation

  - Internal audit and management review
  - Legal and regulatory requirements
  - Customer specific requirements
- NSAI will provide an audit report at the close out meeting; this may or may not contain non-conformances with the applicable Scheme/Standard.
- NSAI will then determine whether to proceed to stage 2 audit assessment

2.2 Stage 2 audit assessment

- NSAI will provide an audit plan and identify audit team members in advance of the audit
- An opening meeting between the Client and NSAI audit team will be held on audit day 1
- A facility tour may be requested
- NSAI will conduct a comprehensive on-site assessment of the quality management system
- Throughout the assessment the NSAI audit team will have regular meetings with the Client to review progress and allocate resources
- In the event it becomes apparent during the audit that the Client is not ready for registration the lead auditor will organise a meeting with the Client's senior management team to advise them of the situation
- The NSAI audit team will analyse the data gathered from stage 1 and stage 2 audit assessments and will determine the audit conclusion
- The information will be passed to the NSAI's medical device operations manager for technical review and assessment
- Upon NSAI satisfaction with the technical review, the audit documentation will be presented to the NSAI certification review committee
- Subject to NSAI's positive determination, Certification will be granted

3 ANNUAL REGISTRATION

Certification registration must be renewed annually.

4 SURVEILLANCE AUDITS

Following the initial certification audit the first surveillance audit typically occurs within 6 months of grant of Certificate..

All subsequent audits will be conducted on an annual basis for ISO 13485 and MDSAP and at least every 12 months for MDR and IVDR.

5 AUDIT NON-CONFORMANCES

Non-conformances are graded as follows:

- ISO 13485: 2016 & EU Regulatory EN ISO 13485:2016
  - Category 1 major non-conformance
  - Category 2 minor non-conformance
  - Category 3 observation or comment

- MDSAP Non-conformances are graded from 1 to 5
  - Grade 5 represents a significantly high risk

6 POST-AUDIT FOLLOW UP

The lead auditor will communicate with the Client and with the NSAI certification review committee to verify that corrective actions are acceptable.

7 3-YEAR REASSESSMENT AUDIT

Except in the case of MDR and IVDR a reassessment audit is conducted at 3-year intervals.

This will include the review of previous surveillance audit reports. If there is a positive audit conclusion and if audit documentation is deemed satisfactory by the NSAI certification review committee, continued Certification will be granted.

8 UNANNOUNCED AUDITS

Unannounced audits will be conducted within the Certification cycle. An unannounced audit cannot be refused and can be extended to critical suppliers and sub-contractors.

9 FOR CAUSE OR SPECIAL AUDITS

For cause or special audits can occur within the Certification cycle and can sometimes occur at short notice. For cause or special audits cannot be refused and can be extended to critical suppliers and sub-contractors.

9 TRANSFER OF EXISTING REGISTRATION

Existing registration transfers are carried out as a transfer activity. Supporting documentation required to complete this activity include:

- Copy of existing Certificates
- Management system documentation (e.g. quality manual, top level procedures)
- Copies of the last audit reports (up to and including last re-assessment) from previous registration Registrar/Notified Body including any corrective action plans or responses as necessary
- Contact with outgoing certification body / notified body / auditing organisation will not be made without customer knowledge and agreed timing.

Following successful transfer and certificate issuance, NSAI will resume Certification activities in line with the current Certification cycle.

11 ADDITIONAL MDSAP SPECIFIC REQUIREMENTS

The client may only object to the make-up of a [MDSAP] audit team by lodging a formal appeal to NSAI.

Non-conformances under [MDSAP] are graded from 1-5; Grade 5 represents a significantly high risk.

All audit conclusions are reported to the [MDSAP] regulatory authorities.

The recertification cycle for [MDSAP] is 3-yearly.

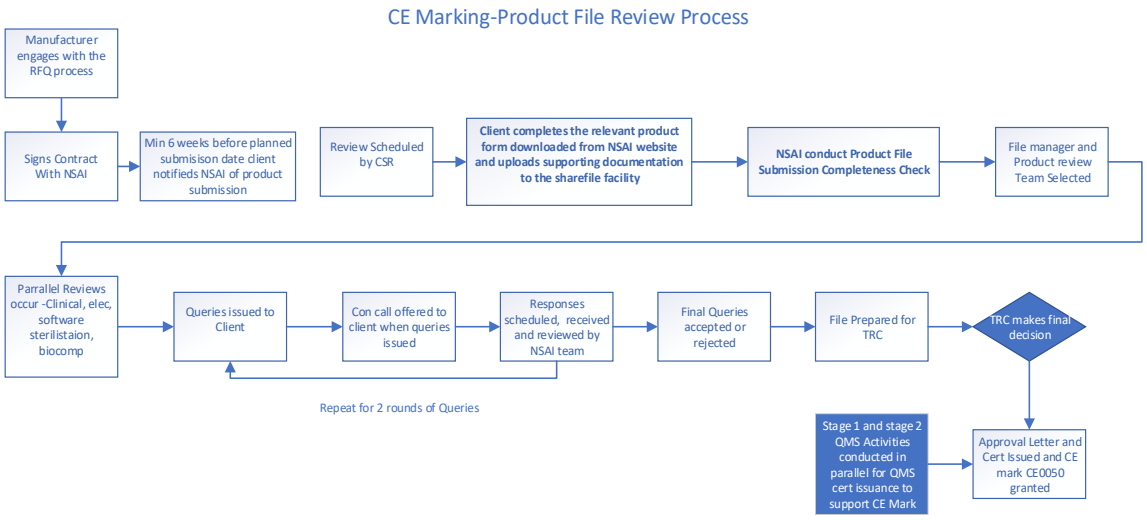
12 ADDITIONAL MDR/IVDR REQUIREMENTS

The recertification cycle for [MDR/IVDR] certificates is 5 years.

Surveillance audits are carried out at least every 12 months.

13 EXPLANATION OF CE MARKING PHASES FOR PRODUCT CERTIFICATION

NSAI will only provide Certification Services for medical device products where NSAI is or will be the certification body for the quality management system.



13.1 Product File Submission Completeness Check

- A separate application must be submitted for each product or product family and for each conformity assessment procedure set down in the Annexes to the MDR or IVDR.
- The product file submission will be reviewed by NSAI to ensure the information in the application form and supporting materials/data is adequate and complete for file manager/project assignment.
- Should the application form and supporting materials/data be incomplete, the Client will be requested to send the missing information.
- Upon receipt of adequate and complete materials/data, an NSAI file manager will be assigned.

13.2 Technical File Review

The NSAI file manager will assign a product review team to the product; the team members will be selected based on competency and classification requirements.

- NSAI will conduct a complete technical review of the product application against the requirements of the applicable EU Directive/Regulation.
- The review time taken will depend on associated risk and classification for the product.
- Upon initial review, the Client will be contacted regarding queries and a conference call offered to discuss.
- The NSAI file manager will agreed with the Client on an expected response date.
- The Client will submit responses via the NSAI up-load facility.

Two additional rounds of queries may occur, if after two rounds NSAI deems the Client responses inadequate, the application will be refused. Should the Client wish to proceed a new application must be submitted.

In the event of an unsuccessful application NSAI will inform the Irish designating/competent authority; the Health Products Regulatory Authority (HPRA).

When the NSAI product review team is satisfied with the closure of the technical queries the file will be presented to the NSAI technical review committee for final approval on grant of certification. For certain products (e.g. novel or high-risk devices) NSAI may require external experts to review the technical file.

Where appropriate, based on the data submitted and outcome of the review, post-approval conditions or restrictions may be applied to the Certificate.

14 POST APPROVAL SURVEILLANCE

All vigilance reports, periodic safety update reports, trend reports, field safety notices and field safety corrective actions are to be supplied to NSAI and Irish competent authority at the same time.

Where applicable, the Client must schedule and submit annually all additional reports such as the Summary of Safety and Clinical Performance Report (SSCPR), the Periodic Safety Update Report (PSUR) and the Post Market Clinical Follow Up Report (PMCFUR).

15 TRANSFERS FROM OTHER NOTIFIED BODIES

All certifications transferred from another EU notified body are treated as new applications and are subject to full conformity assessment.

16 ANNUAL PRODUCT LICENCE

Annual product licence permits the Client to use NSAI's notified body number, 0050, in conjunction with CE marking of their devices.

17 SIGNIFICANT CHANGES

In accordance with EU directives/regulations, NSAI is required to assess significant changes to the product range or quality system that applies to the product. The Client is obliged to notify NSAI of the significant changes.

18 5-YEAR RENEWAL

The 5-year renewal is conducted to review that certified products placed on the market during the previous 5 years remain in compliance with the applicable EU directives/regulations and forms part of the determination of the acceptability of renewal of the CE certificate for a further 5-year cycle.

The review has the objective of ensuring that the Client is compliant with 'state of the art' (e.g. current standards & requirements), and to assess the performance of the device(s) during the period under review.

The review does not include assessment of proposed changes which have not yet come into effect; such proposed changes should be scheduled for assessment separately as significant changes.

Application for 5-year renewal should be submitted to NSAI at least one year in advance of Certificate expiration date.

19 VIGILANCE INVESTIGATION

In the event NSAI is made aware of vigilance issues arising from products placed on the market under an NSAI issued Certificate, NSAI will conduct a vigilance investigation.

20 FEES

NSAI fees are set out in the Quotation Letter for the initial application as published on the NSAI website at that time. Fees are normally based on daily rates and estimates of average number of working days involved in product review, on-site audit activities, and pre and post audit activities. In accordance with clause 8.5 of Schedule 1 the fees are subject to review from time to time. Fees

are billed at the rate effective at the date the fee is incurred. Administrative costs are individually priced.