

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 -

- (EN) ISO 13485:2016
- ISO 9001:2015 in combination with ISO 13485:2016
- EU Regulatory: MDR and IVDR
- 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

MDSAP means the Medical Device Single Audit Program

Medical Device Coordination Group (MDCG) means the expert group established by EU DG Health and Food Safety to provide advice to the Commission and assist the European Commission and the Member States in ensuring a harmonized implementation of medical devices Regulations (EU) 2017/745 and 2017/746.

Stages for Applications

- Application submitted to NSAI using the NSAI online form (RFQ).
- NSAI reviews application and may request clarifications or further information.
- NSAI signed Quotation Letter is sent to applicant in conjunction with Schedule 1 - General Terms and Conditions, Schedule 2 - Special Terms and Conditions (this document).
- 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)
- NSAI reserves the right to release audit report information to regulators that recognize ISO 13485.

2 GENERIC REQUIREMENTS

The Client agrees to provide NSAI with all the necessary documents and information required for NSAI to perform the assignment under this contract.

NSAI may carry out audits remotely, at its discretion.

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 has the right to suspend a current certificate or terminate this agreement, with immediate effect, if the Client fails to address any nonconformances within the timeframes set after a review of the quality management system or technical documentation assessment.

This agreement and resulting certificates are only valid for the Client, and certificates are not transferable to another manufacturer. In the event of a change in ownership, NSAI shall be informed of the change immediately.

The Client is obliged to submit planned significant changes to NSAI for assessment and approval prior to implementation. Significant changes shall be reported to NSAI, on NSAI designated forms and sent to NSAI by e-mail to: medicaldevices@nsai.ie.

Where NSAI utilises a subcontract auditor or product reviewer for conformity assessment activities, that individual meets all relevant NSAI competency and impartiality requirements. Subcontract auditor or product reviewers are precluded from further subcontracting their work to any other organisations or individuals.

3 FEES

NSAI fees are set out in the Quotation Letter for the initial application as published in the price list, available 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.

4 ANNUAL ADMINISTRATION FEE

Certification administration fee must be paid annually according to valid price list. Paid annual administration fee permits the Client to use NSAI's notified body number 0050 in conjunction with CE marking of their devices that are covered by NSAI MDR or IVDR certificates. The client will also be entitled to continue using/referencing all other applicable certificates.

5 OBLIGATIONS TO FOLLOW TIMELINES

The Client undertakes to comply with the timelines for requests for information specified by NSAI. Failure to comply with these timelines may result in certificate withdrawal or additional costs. See further information in Schedule 1 section 8 "Fees".

6 COMPLAINTS AND APPEALS

It is the policy of NSAI to handle and resolve all complaints and appeals in a timely and effective manner. Complaints and Appeals are asked to be submitted through feedback@nsai.ie. The submittal will be assigned to the appropriate NSAI staff member for review and appropriate action. See schedule 1 for details.

7 CERTIFICATE SUSPENSION, WITHDRAWAL OR REDUCTION IN CERTIFICATION SCOPE

The conditions under which a certificate may be suspended or withdrawn are detailed in MCN-1001. In the case of suspension, NSAI shall reinstate suspended certification if the issue that has resulted in the suspension has been resolved. If the certification is withdrawn or suspended, the client must discontinue its use of all matters that contains any reference to a certified status. This means that devices may not be placed on the market or marketed with reference to the certificate or NSAI Notified Body ID number 0050 until a decision has been taken regarding reinstatement of the certificate.

NSAI will reduce the client's scope if the certificate holder ceases to supply a product, process or service for an extended period of time or when the client has persistently or seriously failed to meet the certification requirements or contract arrangements for those parts of the certification scope.

8 AUDIT PROCESS

8.1 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.
- 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
 - The Internal audit, corrective and preventive action, complaint and management review processes
 - Legal and regulatory requirements
 - Customer specific requirements
- NSAI will provide an audit report at the end of the stage I audit or in conjunction to that audit; this may or may not contain nonconformances with the applicable Scheme/Standard.
- NSAI will make an assessment of Clients critical suppliers to recommend potential audits of these needed for certification audit. These identified critical suppliers may be audited at any following audit. These critical suppliers can also be identified during any other audit activities. The Client shall, through agreements with critical suppliers and subcontractors, ensure that NSAI auditors and experts gain access to critical supplier sites.
- NSAI will then determine whether to proceed to stage 2 audit assessment.

8.2 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 assessment of the quality management system. This may be performed on-site, remotely or via a hybrid audit.
- 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 certification the lead auditor will arrange 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 and recommendation.
- NSAI will provide an audit report after the audit. this may or may not contain nonconformances with the applicable Scheme/Standard.
- An independent technical review of the audit documentation is performed.
- Upon NSAI satisfaction with the technical review, the audit documentation will be presented to the NSAI certification review committee (CRC).
- Subject to NSAI's positive determination that all applicable requirements are met, Certification will be granted.

8.3 Surveillance audits

Following the initial certification audit (Stage 1 and Stage 2) the first surveillance audit typically occurs within 6-11 months of grant of Certificate.

All subsequent audits will be conducted on an annual basis (minimally once per calendar year) for ISO 13485 and MDSAP and at least every 12 months for MDR and IVDR. Where possible NSAI will combine these audits.

9 NONCONFORMANCES

Nonconformances are graded as follows:

- ISO 13485 and MDR/IVDR, MDR and IVDR:
 - Major non-conformance
 - Minor non-conformance
 - Observation or comment
- MDSAP Non-conformances are graded from 1 to 5.
 - Grade 1 represents a low risk with indirect QMS impact
 - Grades 4 and 5 represent a significant risk with direct QMS impact

10 POST-AUDIT and POST-TECHNICAL DOCUMENTATION (TD) ASSESSMENT FOLLOW UP

The lead auditor, or TD Assessor, will communicate with the Client and with the NSAI certification review committee to verify that corrective actions, reported by the client as response to nonconformances, are acceptable.

11 RECERTIFICATION AUDIT

Except in the case of MDR and IVDR a reassessment audit is conducted at 3-year intervals. MDR and IVDR certificates requires a recertification activity within five years from date of issue of a certificate. This will include the review of previous surveillance audit reports, If there is a positive conclusion and if audit documentation is deemed satisfactory by the NSAI certification review committee, continued Certification will be granted.

12 UNANNOUNCED AND SHORT NOTICE AUDITS

Unannounced and short notice audits may be conducted within the Certification cycle. These audits cannot be refused and can be extended to critical suppliers and sub-contractors.

If the Client is not available for an unannounced audit, and has not notified NSAI in writing in advance, the cost of an unannounced audit will be charged to the Client. A new unannounced audit will be conducted.

13 FOR CAUSE OR SPECIAL AUDITS

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

14 TRANSFER OF EXISTING CERTIFICATES

Existing certification transfers to NSAI are carried out as a transfer activity provided there is sufficient time to complete the transfer activities prior to a certificate expiration. Supporting documentation required to complete this activity include:

- Copy of existing and valid accredited Certificates or recognized certificates (MDSAP) or MDR/IVDR Notified Body 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 Certification Body/Notified Body/Auditing Organisation including any corrective action plans or responses as necessary.
- For MDR/IVDR copies of the last TD Assessment reports (up to and including last re-assessment) from previous 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.

15 ADDITIONAL MDSAP SPECIFIC REQUIREMENTS

The client cannot object to the composition of the MDSAP audit team. Any concerns related to the audit team composition may be communicated utilizing the NSAI appeals process. The rationale for the appeal will be evaluated to determine its validity.

Unannounced audits will be performed if previous audits indicate serious and/or frequent nonconformities, or if a nonconformity has resulted in the release of nonconforming medical devices. An unannounced audit will be performed following any audit that result in one or more nonconformity(s) graded as a "5" or more than two nonconformities graded as a "4".

Recertification audits must be scheduled with sufficient time to complete the recertification process prior to the end of the certification period. It is not acceptable to have an expired MDSAP certificate.

All audit conclusions are reported to the MDSAP regulatory authorities.

16 ADDITIONAL MDR/IVDR REQUIREMENTS

The maximum certification cycle for MDR/IVDR certificates is 5 years.

Unannounced audits will be conducted within the certification cycle. These audits cannot be refused and can be extended to critical suppliers and sub-contractors.

Any information that emerges during the assessment of the technical documentation and that leads to a change in the scope of the assignment gives NSAI the right to adjust the agreed price in relation to the scope of the change, or alternatively NSAI has the right to resign from the assignment if the changed scope falls outside the areas in which NSAI is a notified body.

NSAI has the right to require that the application or future assessments be supplemented by additional tests or by requiring additional evidence in order to assess the conformity of the device with the relevant requirements of the MDR or IVDR.

If external testing of product should become relevant to complete or supplement a conformity assessment NSAI may have to outsource this testing. This outsourcing is then regulated in a separate agreement.

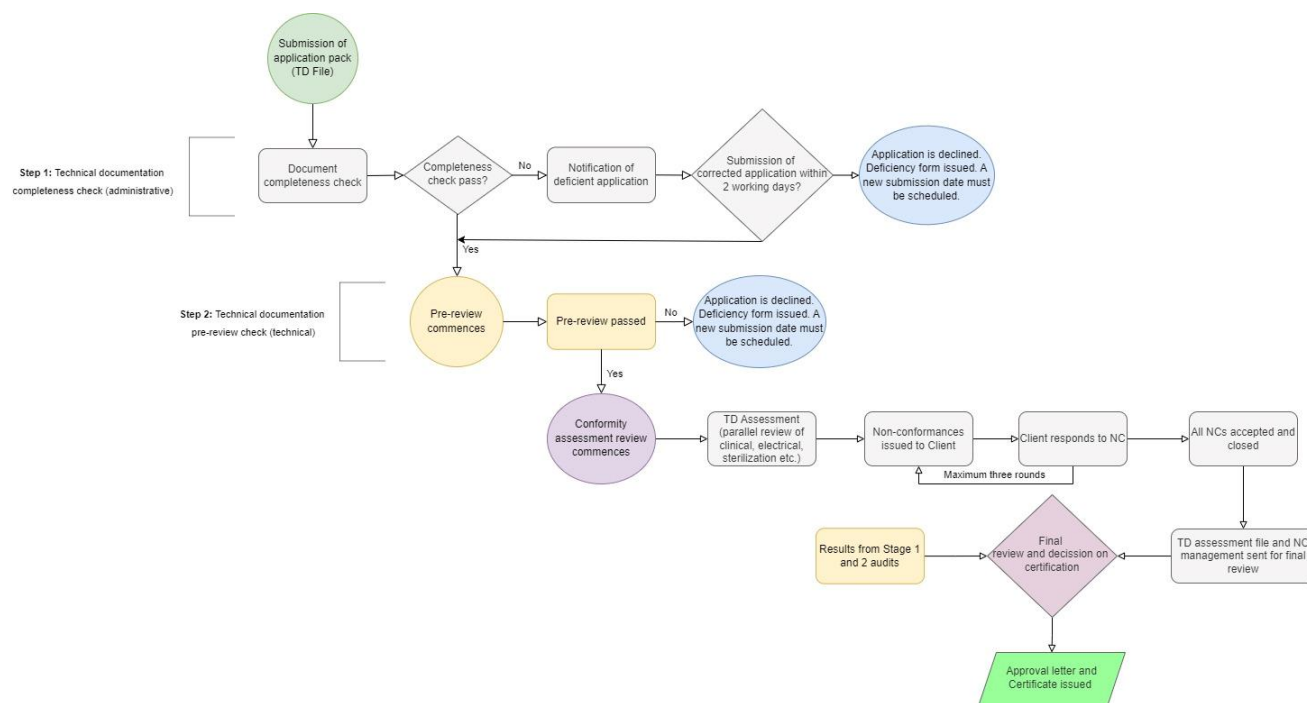
The conformity assessment to the MDR or IVDR that is covered by this agreement applies only directly between the Client and NSAI and not with any other organization.

This agreement and resulting certificates are only valid for the Client, and certificates are not transferable to another manufacturer. In the event of a change in ownership, NSAI shall be informed of the change immediately.

Certificates generated under this agreement are applicable to the devices listed in the device list issued with the certificate.

17 EXPLANATION OF CE MARKING CERTIFICATION UNDER MDR/IVDR

CE Marking-Technical File Review Process



17.1 Technical Documentation Completeness Check

- A separate submission must be lodge for each product or product family and for each conformity assessment procedure set down in the conformity assessment Annexes to the MDR or IVDR. The completed technical documentation product review form and supporting documentation (Data Folder Set) is required to be submitted to NSAI within 30 days from the NSAI request.
Failure to adhere to the timelines for requested Technical Documentation will be charged to the client according to section 8 in Schedule 1.
- Where there are no deficiencies observed, the Technical Documentation pre-review will be conducted. No further action from the client is required in regards to this step.
- If there are deficiencies noted, the client will receive Submission Inspection Deficiency Form with a list of deficiencies that require resolution. The client has 2 working days, from receipt of the Submission Inspection Deficiency Form, to rectify the deficiencies and resubmit the complete product review form and supporting documentation (Data Folder Set) via the NSAI upload portal. This new data will be checked by NSAI. If the deficiencies are resolved, the Technical Documentation pre-review check will be conducted. No further action from the client is required in regards to this step.
- If the deficiencies are not resolved following the additional inspection, the client will receive a deficiency communication and the Submission Inspection Deficiency Form outlining the deficiencies that remain. At this point, NSAI will not proceed with the scheduled review. The client will have the option to schedule a new technical documentation review slot via the process outlined previously. This will be treated as a new submission and will be subject to the full product file submission completeness check and charged as a new submission.

17.2 Technical Documentation pre-review check

After fulfilled completeness check the Technical Documentation pre-review check will commence. Technical Documentation pre-review check will result in the submission processing to full Technical Documentation Assessment or being rejected. There will be no opportunity to respond to non-conformities at this stage.

- If accepted: The file progresses for scheduling with the technical documentation assessment team.
- If rejected: A report will be issued detailing the reason for rejection. In this case, a full resubmission of the technical documentation is required. This process continues until the file is accepted to be moved forward for scheduling with technical documentation review team.

Please note, each submission pre-review check will be billed accordingly.

17.3 Technical Documentation Assessment

NSAI will assign a Technical Documentation Assessment team to the product; the team members will be selected based on competency and classification requirements.

NSAI will conduct a complete technical documentation assessment (review) of the product application against the requirements of the applicable Regulation.

The review time taken will depend on associated risk and classification for the product.

Upon initial review, the Client will be presented with a Technical Documentation Assessment report and potential nonconformances.

Client shall adhere to communicated response date.

The Client will submit responses via the NSAI upload facility.

A maximum of three (3) rounds of responses to resolve the nonconformances may occur, if after three 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 a refused or withdrawn application, NSAI will inform the Irish designating/competent authority; the Health Products Regulatory Authority (HPRA) as well as upload the information to EUDAMED.

When the NSAI product review team is satisfied with the closure of the nonconformances the file, together with the recommendations related to the certification audit will be sent for final approval and decision on certification.

For certain products (e.g. novel or high-risk devices) NSAI may require external experts to review the technical documentation.

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

Additional technical documentation samples are assessed annually and follows the guidelines in the MDCG documents for assessment of technical documentation.

If all technical documentation has been assessed and there is time left in the certification cycle, NSAI has the right to add time on future audits to focus on the review of the technical documentation related to post-market surveillance in accordance with MDR/IVDR Annex III.

18 MDR/IVDR POST CERTIFICATION 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. Please use the following e-mail address for these reports: vigilance@nsai.ie

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 (PMCFR).

19 MDR/IVDR SIGNIFICANT CHANGES

In accordance with EU regulations, NSAI is required to assess significant changes to the product range or quality system that applies to the products. Prior to implementation the Client is obliged to submit planned significant changes to NSAI for assessment and approval. Significant changes shall be reported to NSAI, on NSAI designated forms and sent to NSAI by e-mail to: medicaldevices@nsai.ie.

20 MDR/IVDR 5-YEAR RECERTIFICATION ACTIVITY

For MDR and IVDR certificates the 5-year certification renewal is conducted to review that certified products, and related QMS, placed on the market during the previous 5 years remain in compliance with the applicable EU regulations and forms part of the determination of the acceptability of renewal of the CE certificate for a further maximum 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) and QMS during the most recent certification cycle. This includes the review of Technical Documentation reports and the requirements of MDR/IVDR Annex VII 4.11.

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

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

21 MDR/IVDR 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. Any decision to further investigate the reported vigilance cases will be charged to the Client according to valid pricelist.

22 TRANSITIONAL PROVISIONS CONCERNING VALIDITY OF CERTIFICATES ISSUED IN ACCORDANCE WITH THE IVDD

During the period of transition to the IVDR, certificates granted under the IVDD will remain in force subject to the transitional arrangements set down in the IVDR. NSAI will perform the appropriate surveillance activities of those IVDD certificates in force in accordance with regulations and guidelines of the Medical Device Coordination Group (MDCG) as issued from time to time.