The European Association
Medical Devices - Notified Bodies

Code of Conduct for Notified Bodies

under Regulations (EU) 2017/745 and (EU) 2017/746

"Improving implementation of the European CE certification of medical devices through the harmonisation of Notified Bodies"

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1. General Statement

The work of Notified Bodies ("**NBs**") in the Conformity Assessment and Certification of Medical Devices (MD) and *In-Vitro* Diagnostic Devices (IVD) continues to be a key corner stone of the EU legislative system to safeguard public health. This role creates a strong interest in public opinion and among other stakeholders, such as European and national authorities.

Regulations that entered into force in 2017 (MDR (EU) 2017/745 and IVDR (EU) 2017/746) have an Annex VII dedicated to the Requirements to be met by NBs.

The update to the CoC in 2024 reflects the current applicable legislation and guidance documents. Only aspects of conformity assessment that benefit from some detail to enhance consistency are covered. All references to obsolete legislation (93/42/EEC, 90/384/EEC and 98/79/EC) are removed. References to guidance, standards and mandatory documents from the International Accreditation Forum (IAF) are updated.

Adoption of this CoC continues to be voluntary to NBs and continues to give a clear signal that signatory NBs declare to be fully aware of their responsibility to ensure that certification of Medical Devices complies with the Regulations. Any party with recognized NB status is entitled to sign up to the CoC. The procedure to enable NBs to sign up will be transparent, fair and non-discriminatory.

The signatory NBs aim to ensure a harmonised quality of work amongst the participating NBs, to gain trust in this work in public perception as well as from political and policy stakeholders, to contribute to ensure the trustworthiness of the system amongst international partners of the European Union and to support the reputation of the participating NBs.

By signing this **CoC**, the participating NB commits to a high quality of work by education and training of staff involved, and depth and diligence of the work carried out.

The EU regulations are very new with improved requirements. They are suited to support dynamic innovation while safeguarding patient safety. NBs need to be motivated to adapt rapidly to the ever-changing technological needs, hiring sufficient competent staff and help make new technologies quickly available to patients through efficient and robust approval processes.

Throughout this document, "MD directives" includes the AIMD 90/385/EEC, MDD 93/42/EC and IVD directive 98/79/CE and "MD regulations" includes (EU) 2017/745 and (EU) 2017/746 unless otherwise specified.

Where external documents are referred to, the latest version is used and will be referenced at the end of this document.

By signing this **Code of Conduct for Notified Bodies Regulations (EU) 2017/745** and **(EU) 2017/746**, version 5.0, the participating NB ensures its executives will lead by example and will actively live out and communicate the principles set forth in this Code of Conduct and all staff shall be responsible for ensuring their business conduct complies with it. We will not tolerate any violation and will apply appropriate measures to ensure the application of this Code of Conduct.

Date:
.....

NOTIFIED BODY:
.....

NB number:
.....

Signature:
.....

Name:
.....

Title:
.....

2. General principles of conduct

This Code of Conduct is characterized by loyalty and integrity to patient safety, the requirements of our designation as well as the support of our customers, which is reflected in the following core principles:

- We operate in compliance with recognized regulations, directives and standards, and observe all relevant local and international laws wherever we conduct business.
- We are accountable for our actions to the Competent Authorities and stand by them. Staff are continuously informed and trained to raise their awareness on how to address upcoming issues.
- We are committed to continuous improvement.
- We maintain integrity and build confidence. Management of the participating NB encourages an open atmosphere among their staff and subcontractors to report any potential violations to this Code. Any Conflicts of Interests will be prevented, or in exceptional cases tightly controlled. Data-protection will be in place to protect confidential data. We will ensure that nobody in any role within the NB reviews and reflects on their own work.
- We are compliant to the applicable requirements of the EU medical device regulations and as per MDR/IVDR Annex VII Clause 4.5.1 associated Common Specifications, MDCG guidance, Best Practice Guidance and Harmonised Standards.
- We provide our services independently and professionally in compliance with the relevant regulations or directives and in line with the methods, standards, and processes applicable for NB and set by accreditors and designating authorities.
- We commit to an active participation of our organisation in the NBCG-Med meetings and related MDCG working groups and committees to work on continuing harmonisation between NBs, maintaining state-of-the-art knowledge of and contributing to ongoing regulatory developments and strengthening implementation of the legal framework for medical devices in the European Union.
- We commit to take into consideration the position papers issued by Team-NB and NBCG-Med and to follow as far as possible.
- This version of the CoC is not covering all aspects of the work of NBs but it is our intention to add to this CoC in later stages following engagement with and feedback from various stakeholders.

3. Implementation and monitoring of the Code of Conduct

3.1. Commitment

The Quality Management System and business practice of the Signatories with respect to their medical device NB activities shall be in compliance with this CoC. The Code is a set of rules to which all Signatories and their employees have pledged their commitment. It is signed by an authorized representative within the participating NB.

By signing this CoC, the participating NBs commit to adoption and publication of detailed and transparent enforcement measures for this CoC based on the principles and options defined in this chapter.

3.2. Enforcement

This CoC will be implemented by the signatory NB within twelve (12) months from the moment of signing the CoC, without conditions.

The CoC does not require retrospective implementation for all existing contracts. It shall apply for all new contracts, applications and re-certifications within twelve (12) months following signature.

The signatory NB will commit to including the requirements of this CoC version 5.0 in their internal audit program within twelve (12) months following signature.

Peer-assessment as implemented in previous versions of the CoC are discontinued, because the Regulations now contain a clear Annex with requirements specifically for NBs which are very prescriptive. Furthermore, all NBs are subjected to Joint Assessments ensuring further harmonisation.

This CoC can only fulfil its purpose effectively if it is enforced strongly among all Signatories and adequate remedies are taken in case of structural non-compliance. All Signatories are committed to find ways of implementation and enforcement that are effective, transparent and will lead to structural harmonisation and securing of the quality level of NBs. Complaints related to not following the CoC will result in an investigation by Team-NB.

4. Qualification and Assignment of Notified Body Assessment Personnel

The qualification codes for NB assessment personnel are described in Implementing Regulation (EU) 2017/2185, MDCG 2019-14 (MDR) and MDCG 2021-14 (IVDR). These codes form the basis to identify the competence of the NBs later published on NANDO.

Personnel within the NB complete NBOG F2017-7 (MDR) or NBOG F2017-8 (IVDR) or an equivalent to document competence.

Qualification and requalification criteria for Site Auditors, Product Reviewers, Project Leaders, Internal Clinicians, Clinical Specialists, Final Reviewers, Decision Makers, Authorising Personnel is provided in NBOG 2017-2.

Where a NB adopts the codes described in (EU) 2017/2185 documented on NBOG F2017-7 (MDR) or -8 (IVDR) into its Quality Management System, the NB is assumed to be compliant with this Code of Conduct. Where a NB has implemented a different qualification model, it must ensure that this model at least guarantees an equal or higher level of quality of its assessment staff.

5. Minimum time for Notified Body assessments

This part of the CoC provides guidance for NBs to develop their own documented procedures for determining the amount of time required for the auditing and technical documentation (TD) review of clients and devices of different sizes and complexity over a broad spectrum of activities. It is intended that this will lead to consistency of audit duration and TD assessment duration between NBs, as well as between similar clients of the same NB.
NBs should identify the audit duration for the stage 1 and stage 2 initial audit, surveillance audits, and re-certification audits for each applicant and certified client.
NBs should identify the TD assessment duration for TD assessment, sampling and recertification assessment of devices for each applicant and certified client.
This part of the document does not stipulate minimum/maximum times but provides a framework that should be utilized within a NB's documented procedures to determine appropriate audit and TD review duration, taking into account the specifics of the client.
Time needed for technical documentation reviews should be calculated separately. This time may be added to the onsite audit time or used for off-site reviews.

5.1. Application for audits

5.1.1. Audit Duration

Audit duration for all types of audits includes on site time at a client's premises and time spent off-site carrying out planning, document review, interacting with client personnel and report writing. The time spent for these off-site activities are calculated independently from the onsite audit duration time. At least 80% of the minimum audit time as specified in document IAF MD9 should be spent auditing (on-site, remote, hybrid). NBs will consider using hybrid auditing techniques in line with regulatory requirements. This applies to initial, surveillance and recertification audits. Where additional time is required for planning and/or report writing, this will not be accepted for justification to reduce on site audit duration for any audit. Each participating body has the liberty to define needed off-site time based on its own rules. This CoC only defines minimum criteria for 'audit' time.

5.1.2. Auditor Day

The various rules and tables present audit durations calculated in auditor days on the basis of 8 hours per day. National adjustments on the number of days may be needed to comply with local legislation for travel, lunch breaks and working hours, to achieve the same total number of hours of auditing. The number of auditor days allocated should not be reduced at the planning stages by programming longer hours per working day.
Extension of an auditor day up to 10 hours is allowed in duly substantiated cases based on difficult travel situations.

5.1.3. Effective Number of Personnel

The effective number of personnel at the manufacturer is used as a basis for calculation of audit duration following guidelines in IAF MD9 and IAF MD5. Dependent upon the hours worked, part-time personnel numbers may be reduced and converted to the number of full-time equivalent (FTE) personnel. Specific consideration may be given to those operations where the majority of employees are not located on site (e.g. sales and technical service personnel), working in multiple shift operation (24 hours a day / 7 days a week) or performing identical tasks.

5.2. Methodology for determining audit duration

- The basis for calculation of required audit time is the table in Annex D of IAF MD9. When performing a regulatory audit to the Regulations, time needs to be added to cover all required clauses. Various other criteria may apply for adding or subtracting time which are defined in this CoC.
- Calculation of time for surveillance and recertification audit time should follow the standard principles of IAF MD5.
- All rules of IAF MD9 and IAF MD5 apply.
- It is appropriate to base audit duration on:
    - the effective number of personnel of the organisation
    - the complexity of the processes within the organisation
    - the nature and the characteristics of the medical devices included in the scope of the audit
    - the different technologies that are employed to manufacture and control the medical devices
- The audit duration should then be adjusted based on any significant factors that uniquely apply to the organisation to be audited. The NB should exercise discretion to ensure that any variation in audit duration does not lead to a compromise on the effectiveness of audits.
- Audit duration determinations as specified in this section should not include the time of “auditors-in-training” or the technical documentation assessment.
- Guidance for Hybrid audits are laid down in Team-NB Position Paper - Hybrid Audits. Also refer to IAF MD4.
- The duration of any scheduled-on site audit as part of the annual audit cycle cannot be less than 1 auditor/day (with the exception of small companies).

The locations identified in the audit program should be physically visited at least once per certification cycle.

5.3. Calculation

Using the tables below the appropriate factors should be considered. If a factor is appropriate but no adjustment is used, the justification should be recorded along with the calculation. The % adjustments for all the appropriate factors, both + an – should be

totalled and then applied to the initial IAF MD9 number of days based on employee numbers. To this number of days should be added any adjustments where the adjustment is given in the table as days. If these adjustment calculations would result in a time less than 80% of the initial MD9 number of days than 80% of the initial IAF MD9 number of days should be used as the minimum audit duration. In case of combined audits, e.g. Medical Device Regulation and ISO 13485, additional time is needed.

5.4. Factors for adjustment of audit duration

Increase in audit duration:

List of factors where an increase of the nominal time must be considered and must be applied if appropriate	**Consequence on the nominal on site duration (at least…)**
Several medical devices Regulations included in the scope of the audit and/or Several conformity assessment routes for different devices and/or Significant number of certificates / types	+10%
Audit scope including class III, Class D devices	+10%
Number of MDA or MDN (MDR) or IVR (IVDR) codes included in the audit scope	+10% if more than 3 (and so on by group of 3)
Manufacturers using suppliers to supply processes or parts that are critical to the function of the medical device and/or the safety of the user or finished products	+0,5 day
Manufacturers who install product on customer's premises (time to assess actual installation) (MDT 2012) – MDR only	+0,5 day
Poor regulatory compliance by the manufacturer (with evidence in previous audit reports)	+10- 30%
Complicated logistics involving more than one building or location where work is carried out. e.g., a separate design centre must be audited, particular manufacturing conditions	+10%
Staff speaking in more than one language (requiring interpreter(s) or preventing individual auditors from working independently)	+10%
Very large site for the number of personnel included in the scope of the audit	+10%
Number of additional shifts to be audited, which do not perform identical activities	+10%
System covers highly complex processes (e.g. software design and validation) or relatively high number of unique activities (e.g. more than 3 MDT codes) for MDR	+10%
System covers highly complex processes (e.g., production of reagents, instrument and software or different production technology for reagents such as immunoassay, clinical chemistry, NAT assay, Microbiology (culture) for IVDR	+10%
Activities that require visiting temporary sites to confirm the activities of the permanent site(s) whose management system is subject to certification.	+0,5 day
Manufacturing in clean rooms and / or in-house sterilization activities (MDT 2008, MDS 1005, IVT2008, IVS1005)	+0,0 – 1 day / type of process

Decrease in audit duration:

Factors justifying the potential reduction of the nominal time	**Consequence on the nominal on site duration**
No design activity included in the scope of the audit	Maximum -15%
Audit scope including only low risk products (class IIa, class B and less) or simple manufacturing processes	Maximum -15%
Maturity of management system (certified for more than two certification cycles + with evidence of performance of the QMS in previous audit reports)	Maximum -20%
Client preparedness for certification (e.g., the company is already certified by NB/CB itself or another certification body according to ISO 13485)	Maximum -15%
Client preparedness for certification (e.g., the company is already certified by NB/CB itself or another notified body according to medical devices regulations (different scope) and ISO 13485)	Maximum -15%
Prior knowledge of the client management system (e.g., already certified to another QM standard by the same NB)	Maximum -15%
Low complexity activities/ Processes involve a single generic activity	Maximum -15%
Identical activities performed on all shifts with appropriate evidence of equivalence performance on all shifts based on prior audits (internal audits and NB audits);	Maximum -15%
Where a significant proportion of staff carry out a similar simple function.	Maximum -15%
Where staff include a number of people who work "off location" e.g. salespersons, drivers, service personnel, etc. and where it is possible to substantially audit compliance of their activities with the system through review of records.	Maximum -15%
Outsourcing of most of the manufacturing processes (for all the medical devices included in the audit scope)	Maximum -15%

All attributes of the client's system, processes, and products/services should be considered, and a fair adjustment made for those factors that could justify more or less auditor time for an effective audit. Additive factors may be offset by subtractive factors.

In case of any change in the situation of the manufacturer's situation having implications on the certification scope, the audit duration should be recalculated. Where necessary, additional time, defined separately, is dedicated for each site / supplier to be audited.

5.5. Multi-site audit scheme

Certification of Multiple Sites under one Quality Management System based on sampling as defined in IAF MD1 guidance document (Multi-site auditing) is in principle not an option for Conformity Assessments. Rare exceptions must be substantiated. An example is the situation where there is no actual work performed at the legal address (e.g. a home address) and the actual work is performed at a secondary location(s).

5.6. Estimation of time needed for technical documentation (TD) assessment

The table below can be used to make an estimation of the time needed for the first round TD assessment, either as part of sampling of devices according to Annex IX or Annex XI part A (MDR) / Annex XI (IVDR) or for TD assessment to Annex IX, section 4 or Annex X. Time for assessment of solutions to non-conformities and questions is not included. As experience with MDR/IVDR grows NBs should use the MDCG 2023 2 template to give an estimate of total cost.

One day constitutes 8 hours.

The time can be increased if needed because of the technical or clinical complexity of design and manufacturing of the device (e.g. novelty of medical indication, multiple indications, multiple analytes, need for external experts, the way devices are grouped etc.). **Additional time might also be necessary if the TD is of low quality, not sufficiently structured or not readily searchable.**

The time can be decreased if the TD assessment is done because of a review of a change to a previous sampled device, if the sampled device is very much alike a previous reviewed device (e.g. they share one single clinical evaluation report) or if it concerns a re-certification TD assessment of an already reviewed TD in an earlier certification cycle.

MDR:

AIMD	MDA0101-0104	8-18 Days
Active	MDA0201-0204	4-8 Days *greater if systems
	MDA0301-0318	4-8 Days *greater if systems
Implantable	MDN1101-1104	4-8 Days *greater if non-WET or system
Non-Implantable	MDN1201-1214	4-8 Days *greater if systems
Medicines & Human Blood Derivatives	MDS1001	+2-3 Days per substance
Human Tissue	MDS1002	+2-3 Days
Animal Tissue	MDS1003	+2-3 Days *greater if TSE susceptible and subject to (EU) 722/2012
Biological Substances		+2-3 Days
Machinery	MDS1004	+0.5-1 Day
MDR Rule 21		+2-3 Days per substance
Sterile	MDS1005	If Class Is – TD aspects reviewed per Article 52(7) +0.5-4 Days *greater if large range of diverse devices covered
Reusable Surgical Instruments	MDS1006	If Class Ir – TD aspects reviewed per Article 52(7) +0.5-1 Day
Nanomaterials	MDS1007	+1 Day
Biological Coating / Absorbed	MDS1008	+1 Day
Software	MDS1009	+1-3 Day

Measuring	MDS1010	If Class Im – TD aspects reviewed per Article 52(7) +0.5-1 Day
Procedure Packs	MDS1011	TD aspects reviewed per Article 22(3)
No Medical Purpose	MDS1012	+1 Day
Class III custom-made implant	MDS1013	TD aspects reviewed per Article 52(8)
Incorporating IVD	MDS1014	+1-4 Days

IVDR:

Class B		4-8 Days
Class C		4-8 Days
Class D		4-8 Days
Absence of Common Specification		+1-2 Days
Absence of EURL		+1-2 Days
Near Patient Test	IVS1001	+0.5-1 Day
Self-Test	IVS1002	+0.5-1 Day
Companion Diagnostic	IVS1003	+1 Day
Tissues or Cells of Human Origin	IVS1004	Included
Sterile	IVS1005	If Class As – TD aspects reviewed per Article 48(10) +0.5-2 Days *greater if large range of diverse devices covered
Calibrators	IVS1006	Included
Control Materials with Assigned Values	IVS1007	Included
Instruments, Equipment, Systems	IVS1008	+0.5-1 Day
Software for analysis, monitoring	IVS1009	+1-3 Days
Controlled by Software	IVS1010	+1-3 Days

6. Technical documentation assessment

Technical documentation assessment is required for initial certification under MDR or IVDR. It is performed either systematically for high-risk class devices or on sampling basis. The role of the NB is described in Article 52 MDR / 48 IVDR, some devices are subject to technical documentation assessment based on sampling.

6.2. Systemic technical documentation assessment

The following devices are subject to technical documentation assessment pursuant to Annex IX Chapter II or Annex X of MDR/IVDR.

Device	Reference to Regulation
MD Class III	MDR article 52.3
MD Class IIb Implantable (except WET)	MDR article 52.4 2nd and 3rd subparagraph
IVD Class D	IVDR article 48.3 and 48.4
IVD Class B and C: - Self-testing device (ST) - Near Patient testing device (NPT)	IVDR article 48.7 2nd subparagraph

The NB performs a thorough assessment, taking into consideration common specifications, guidance, best practice documents and harmonised standards.

The NB will, where applicable, proceed to a consultation to the concerned Authority, Expert Panel, Reference Laboratory or European Medicines Agency.

6.3. Sampling of MD / IVD technical documentation

The Sampling of MDR Class IIa / IIb and IVDR Class B / C devices is laid down in MDCG 2019-13.

6.4. Product line additions

The addition of a device in the product range covered by the issued certificate will be the subject of a technical documentation assessment in the following cases:

- class III/IIb implantable
- class D IVD
- class B or C self-testing or Near Patient Testing device
- device belonging to a new Device Group for class IIb device / C IVD device (sampling method)
- device belonging to a new Device Category for class IIa device / B IVD device (sampling method)

The addition of class IIa/IIb or B/C to an already certified category/generic group within the range of products covered by the certificate does not necessarily lead to the TD assessment. The sampling plan of the NB will however be updated to be in line with MDCG 2019-13 guidelines.

7. Unannounced Audits

Increased consideration of unannounced audits is described in Recommendation 2013/473/EU and Implementing Regulation EU/920/2013. When the Directives were superseded by the Regulations in 2017 the details from the 2013 recommendation and regulation may not have been considered by MDR and IVDR NBs. As a way to harmonise, some of the words from those documents are included.

7.1. Basic principles

- Unannounced audits shall be set up and executed by NBs separately from and in addition to the regular audit cycle.
- All elements of unannounced audits shall be conducted by an appropriately qualified audit team.
- The unannounced audits are product focused audits. All audited elements are geared towards the sampled device(s).
- When a manufacturer has multiple certificates under multiple EU legislations, the plans should ensure that individually certified product scopes are covered by the plan in a traceable manner.

7.2. Key definitions

MDR and IVDR have definitions of manufacturer, supplier and subcontractor. Unannounced audits can be conducted at any of these locations. A rationale for sampling any particular site should be documented.

Examples:

- Subcontractor involved in the design or development of a medical device
- Subcontractor involved in the design or development of software
- Supplier/subcontractor of finished medical devices
- Subcontractor that performs critical manufacturing process or compliance check(s) for which any deviations from specifications will impact the safety and/or the claimed essential performance(s): cleaning, sterilization, primary packaging, ...
- Subcontractor in charge of post market data collection
- Suppliers of raw materials for implantable medical devices (e.g.: silicone for breast implants)
- Supplier of materials of animal origin, active substances
- Supplier of radioactive seeds to treat cancer
- Supplier of critical components/sub-systems such as: Suppliers of Printed Circuit Boards, X-Ray Tubes, digital detectors, piezoelectric components mounted on ultrasound probes, ultrasound probes, ECG Electrodes

7.4. Unannounced audit methodology

- The unannounced audit should be based on verifying conformity of a recently produced adequate sample (product, batch, lot) of an approved device type.
- The unannounced audit should be a traceability audit based on the following principles:
    - Selection of one or more catalogue numbers (individual device types) attached to a declaration of conformity, linked to a valid CE certificate.
    - Selection of a random recent batch or lot from those catalogue numbers
    - Requesting for those batches or lots the relevant documentation covering the full process from incoming raw materials and components till final release (Batch or lot history records, manufacturing traveler, bills of materials, etc).
    - Audit the process backwards from final release to incoming materials and components and during this audit verify the following aspects.
        - That the raw materials and components are the same as those specified in the technical documentation of the approved device or device family.
        - That the equipment used in the manufacturing process is still the same compared to the specifications given in the technical documentation of the approved device or device family.
        - That incoming, in-process and final inspection steps are the same compared to the documentation based on which approval was given.
        - Compare testing results done (either physical, electrical, chemical, mechanical or other) on a sample or 100% basis during in-process or final inspection with equal testing done during design verification to ensure device specification are still the same as when the device was approved.
- Apart from auditing documentation, the NB should also where possible witness selected tests to verify test data fall within the specifications. Where appropriate, more testing coordinated by the NB might be required.
- Take into account during the audit process the applicable controlled changes that the device has undergone within the scope of approval issued by the NB.
- A report with findings should be delivered following the assessment.

In case the manufacturer has subcontracted one or more critical parts of manufacture either to own manufacturing locations or to suppliers and they are regarded significant for the safety and performance of the device under review, then the NB needs to determine whether those sites need to be audited as part of the unannounced audit.
In case the NB determines that it can assess traceability and equivalence between the manufactured lot or batch and the approved device without auditing those significant additional sites (manufacturing locations and/or subcontractors), then this should be duly substantiated.

- Manufacturers must have appropriate contracts with their subcontractors and with suppliers that allow an unannounced audit by their NB.

- Subcontractors that have already undergone an unannounced audit in the last 12 months, may be eligible for waiving the need to undergo another unannounced audit. This is at the discretion of the NB performing the unannounced audit.

7.5. Frequency

- An unannounced audit must take place at least once per 5 years per MDR/IVDR Annex VII 4.5.1 and 4.10 in addition to Annex IX 3.4
- The frequency of unannounced audits can increase dependent upon:
    - If the devices are high risk
    - Devices are often non-compliant
- An unannounced audit may take place for specific reasons e.g. suspicion of nonconformities of the devices or manufacturer

<u>Devices that are often non-compliant</u>
Reasons for increased unannounced audit frequency as listed above under this category could be:

- Post-market feedback that the NB receives, such as vigilance cases in an unusual high frequency.
- Very high complaint rates observed during the regular audit schedule, compared to industry norm on that type of product(s).
- Very high number of non-conforming products in manufacturing observed during the regular audit schedule.
- When the non-compliance is no more applicable thus the audit frequency is considered in normal conditions.

<u>Specific reasons for suspicion of nonconformities of the devices or manufacturer</u>
Reasons for increased unannounced audit frequency as listed in the table above under this category could be:

- Any of the reasons listed above
- Other input received through Authorities or news media about possible malfunctioning devices or fraudulent manufacturers.

7.6. Where to audit

- The whole supply chain should be taken into consideration when determining where to perform an unannounced audit: the legal manufacturer, manufacturing locations, subcontractors.
- The same principles apply as in a normal Conformity Assessment with respect to determining when a subcontractor should be part of the unannounced audit.

7.7. Unannounced audit duration

- The typical unannounced audit is completed by two auditors with a duration of one day (an audit day constitutes 8 hours).
- The unannounced audit should be completed with competent people required to cover code described in (EU) 2017/2185 for the selected device(s).
- A rationale can be documented for completion by one auditor or for the reduction of the duration.
- In all other cases where there at least final inspection takes place at the legal manufacturer; the minimum duration of the unannounced audit should be 1 day.
- The NB should define the suitable appropriate duration for the unannounced audits to additional sites (manufacturing locations and/or subcontractors) and should document the rationale for determining the appropriate duration.

8. Renewal / Re-certification

8.1. QMS Certificates

- Confirmation from manufacturer that they wish to go ahead with the renewal – thus signing a 'new application'
- No need for a separate recertification audit, if the regulatory requirements (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
- No need for full or partial TD assessments, if the surveillance sampling is completed
- Follow guidance in MDCG 2019-6
- There must be a final review and decision-making step that consider the above aspects as part of recertification

8.2. Product Specific Certificates

Requirement from Annex VII Clause 4.11	Comments on whether already covered during surveillance or not	To be assessed as part of recertification
(a) all changes to the originally approved device, including changes not yet notified,	This is a complete list of all changes, including some that are not reviewed in surveillance – however changes which are reviewed during the cycle these would be reviewed.	Yes; Summary of changes to verify NB has been informed.

Requirement from Annex VII Clause 4.11	Comments on whether already covered during surveillance or not	To be assessed as part of recertification
(b) experience gained from post-market surveillance,	Covered as part of PSUR assessments.	Yes; Confirm PSURs have been reviewed as per sampling plan. Confirm latest PSUR is on EUDAMED to ensure continued safety and performance of the device. If not carried out, complete the PSUR review before recertification. *Self test, NPT and CDx
(c) experience from risk management,	This complete experience, may not have been covered in surveillance.	Yes; Manufacturer to present information on how any new identified risks or any changes to information on incidence and severity of previously identified risks has been addressed.
(d) experience from updating the proof of compliance with the general safety and performance requirements set out in Annex I,	This complete experience, may not have been covered in surveillance.	Yes; Manufacturers to present updated GSPR checklist and include details of where evidence to compliance has changed.
(e) experience from reviews of the clinical evaluation, including the results of any clinical investigations and PMCF,	Partial coverage will occur as part of PSUR, SS(C)Ps, change reviews. This complete experience, may not have been covered in surveillance.	Yes; Clinical review to include changes since first certification.
(f) changes to the requirements, to components of the device or to the scientific or regulatory environment,	This complete experience, may not have been covered in surveillance.	Yes; Reviewed during recertification- manufacturer to confirm how these have been captured and updated in technical documentation. Any changes to be reviewed by NB. This would be linked to the GSPR checklist update.
(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,	This complete experience, may not have been covered in surveillance.	Yes; As e, f and g- confirmation from manufacturer and verified

Requirement from Annex VII Clause 4.11	Comments on whether already covered during surveillance or not	To be assessed as part of recertification
— 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.		during renewal assessment by NB.
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.	This complete experience, may not have been covered in surveillance.	Yes; Covered as part of b and e.

9. Voluntary Change of Notified Body (Transfer)

Prior to the transfer of certificates, the NB will assess the agreement per Article 58 MDR / 53 IVDR. The Team-NB Voluntary Transfer Agreement should be used.

11. Expert Panels

Under MDR, NBs submit Class III implantable devices and Class IIb active devices under Rule 12 that administer or remove medicinal substances to the Expert Panels. Exceptions to this are described in (EU) 2017/745 Article 54. Under IVDR, NBs submit the first of type Class D devices to the Expert Panels, when no Common Specification exists.

Team-NB facilitates meetings between Clinicians to learn from all opinions and views published by the Expert Panels.

12. Corrective and Preventive Action

NBs conduct conformity assessment through at least quality management system audits, technical documentation assessments and unannounced audits. Audits can result in non-conformities. To harmonise the way that corrective and preventive action plans are handled the following response times should be applied:

Maximum amount of time for the manufacturer to submit Corrective Action Plan (CAP) – 1st time	Up to 30 days
Maximum amount of time for NB to review submitted CAP and either accept or reject	Up to 30 days
Maximum number of attempts a manufacturer has to submit an acceptable CAP	Up to 3 / Up to 90 days
Maximum amount of time for completion of correction on Technical Documentation / Device under review	Up to 365 days
Maximum amount of time for corrective action on other Technical Documentation / Devices impacted by NC raised	Up to 365 days* *Longer timelines may be accepted for manufacturers with a large portfolio of devices

13. Structured Dialogue

MDCG 2022 14 published in August 2022 encouraged NBs to organise structured dialogue with manufacturers before and during conformity assessment. The aim was to enhance the efficiency and predictability of conformity assessment, while not consulting.

NBs can discuss (non-exhaustive examples):

- Project plans
- Submission requirements
- Requirements for reporting change
- Use of guidance, standards and common specifications
- Costs and timelines

NBs cannot (non-exhaustive examples):

- Complete gap analyses
- Check for MDR/IVDR readiness
- Review mock files for MDR/IVDR conformity
- Provide technical solutions
- Explain how the manufacturer should meet specific regulatory requirements

There may not be a need for Structured Dialogue if information is provided in Best Practice Guidance Documents.

Further examples were agreed in MDCG 2019 6 Revision 5 after February 2025.

14. Subcontracting

NBs are at all times responsible for the granting, maintaining, renewing, extending, reducing, suspending or withdrawing of EU certificates. In order to fulfil this responsibility, they are responsible for the execution of the whole certification process (including all the technical aspects of the commercial proposals), as outlined in section 5.2.5 of the Blue Guide 2022. These roles are also defined in MDR & IVDR Annex VII 3.4.1 as written "The following activities may not be subcontracted by NBs:

- review of the qualifications and monitoring of the performance of external experts;
- auditing and certification activities where the subcontracting in question is to auditing or certification organisations;
- allocation of work to external experts for specific conformity assessment activities; and
- final review and decision making functions."

and 4.1. the following requirements shall be fulfilled as part of the internal activities and shall not be subcontracted (refer also to requirements MDCG 2019-4 Rev. 4). See

4.3. Application review and contract
4.4. Allocation of resources
4.7. Final review
4.8. Decisions and Certifications

If necessary, NBs may outsource or subcontract some stages of the assessment process through contracts or agreements. Procedures with criteria for selection of experts and assessors should be in place for any outsourced part of the assessment.

The requirements for any subcontracted tasks are at the same level as what is expected for personnel who works within the NBs organisations. Policies pertaining to outsourced work should include details on:

- Competence and experience;
- Confidentiality;
- Conflict of interests;
- Control of the subcontracted/outsourced services.

Recognising that separate notification (accreditation or designation) for subcontractors is not necessary, external personnel and external laboratories working on behalf of a NB must comply with the requirements of the Annex VII (EU) 2017/745, Annex VII (EU) 2017/746. This is also applicable for employees of affiliated companies. The outsourced work must be carried out following procedures approved by the designating authority monitoring that NB.

Subcontracted parties are not allowed to subcontract parts of the contract to other subcontractors.

Records of the qualification of external personnel and external laboratories must be kept by the NB, as well as evidence on regular monitoring on this established competence and

the correct fulfillment of the outsourced work. A register of all subcontracting activities should be kept.

15. Certificate Falsification

NBs may become aware of suspected falsification, alteration or unauthorised use of certificates that they have issued.
Examples may include (among others):

- Change to manufacturer's name and/or address
- Addition of devices which are not covered by certificate or the applied conformity assessment procedure
- Change of issue, validity or expiry dates
- Alteration of the certificate scope, notified body details or other certificate information

NBs should ensure that they have a QMS process in place to take appropriate actions upon identification of a falsified certificate.

Actions may include, for example:

- Registration of issue in the NB's QMS
- Investigation to determine the nature and, where possible, source of the suspected falsified certificate, using input from relevant technical experts and legal expert advice, as required
- Preservation of relevant evidence
- If falsifier can be identified, informing the falsifier and requesting necessary corrective action. Further legal action may be considered if falsifier does not take appropriate measures. Following an appropriate assessment, informing relevant parties of the identified falsification or misuse of the certificate, where this is considered necessary and proportionate. Relevant parties may include the competent authority, the legal manufacturer (certificate holder) and/or authorized representative as appropriate. Notifications shall take account of applicable confidentiality, data-protection and legal requirements.

Note: Notifications should be based on an appropriate assessment and be proportionate in light of the nature, credibility and potential impact of the falsification or misuse. Notification at the stage of a mere suspicion may be disproportionate and could cause reputational harm, commercial disruption, or legal disputes if the issue later proves to be a misunderstanding or an administrative/document-control error.

16. ANNEX A – REFERENCES

The intent of this CoC is to provide requirements for NBs and their subsidiaries that adhere to this Code, in addition and while adhering to existing requirements and guidance. Some of these existing requirements and guidance documents are referenced below:

1. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC
2. Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU
3. IAF MD 1:2023 IAF Mandatory Document for the Audit and Certification of a Management System Operated by a Multi-Site Organisation
4. IAF MD 5:2023 Determination of Audit Time of Quality, Environmental, and Occupational Health & Safety Management Systems
5. IAF MD 9:2023, IAF Mandatory Document for the Application of ISO/IEC 17021-1 in the Field of Medical Device Quality Management Systems (ISO 13485)
6. NBOG Designating Authorities Handbook – https://www.nbog.eu/nbog-documents/
7. COMMISSION RECOMMENDATION No 2013/473/EU of 24 September 2013 on the audits and assessments performed by notified bodies in the field of medical devices
8. COMMISSION IMPLEMENTING REGULATION (EU) No 920/2013 of 24 September 2013on the designation and the supervision of notified bodies under Council Directive 90/385/EEC on active implantable medical devices and Council Directive 93/42/EEC on medical devices
23. COMMISSION IMPLEMENTING REGULATION (EU) 2017/2185 of 23 November 2017 on the list of codes and corresponding types of devices for the purpose of specifying the scope of the designation as notified bodies in the field of medical devices under Regulation (EU) 2017/745 of the European Parliament and of the Council and in vitro diagnostic medical devices under Regulation (EU) 2017/746 of the European Parliament and of the Council
24. NBOG 2017-2 Guidance on the Information Required for Conformity assessment bodies' Personnel Involved in Conformity Assessment Activities
25. MDCG 2021 17 Applied-for scope of designation and notification of a Conformity Assessment Body – Regulation (EU) 2017/745 (MDR)
26. MDCG 2021 18 Applied-for scope of designation and notification of a Conformity Assessment Body – Regulation (EU) 2017/746 (IVDR)
27. NBOG F2017-7 Review of qualification for the authorisation of personnel (MDR)
28. NBOG F2017-8 Review of qualification for the authorisation of personnel (IVDR)

17. ANNEX B – Assessment of CoC Compliance

Executive Committee of TEAM-NB

Members of the executive committee will sign a confidentiality statement. These will be available on the members part of the TEAM-NB website.

Suspension and/or cancellation of membership of TEAM-NB

- When a complaint investigation concludes there is non-compliance of the CoC and no effective remediation plan is provided within 6 months, the executive committee will decide on the suspension of the member within 1 month.
- In the letter of suspension, clarification should be given on what steps need to be taken, including timelines and communication methods, in order for the suspension to be lifted. Clear identification should be included on the elements that will result in final cancellation of membership of TEAM-NB based on consistent non-compliance to elements of the Code of Conduct.
- Suspension and cancellation letters will be posted on the members only part of the TEAM-NB website.
- In the event of suspension of a member NB, it will remain on the NB listing with the 'suspended' status, until the suspension is resolved or the membership of the NB is cancelled.
- Upon cancellation of membership, the name of the NB will be removed from the membership list displayed on the website.

Appeal process:

- Each NB has the right to appeal against the result of the assessment as well as against the decision of the executive committee. Such appeal should be made available in written format to the executive committee.
- Once an appeal has been brought forward, an independent Appeal Board will be established, consisting of a representative of three NBs member of TEAM-NB that are not liaised with the NB filing the appeal, nor should these members be represented in the executive committee. The NBs in the appeal board will be appointed by the managing director of TEAM-NB, at his/her sole discretion.
- The Appeal Board will evaluate the appeal and communicate the result of the evaluation to all,
    - the NB who did appeal
    - the members of the assessment team
    - the members of the executive committee
- The conclusion of the appeal process will be provided on the member's only section of the TEAM-NB website.

Maintenance of the programme:

- An annual meeting is held for all members of TEAM-NB specific to the Code of Conduct assessment scheme. Such meeting maybe combined with a plenary meeting of TEAM-NB.
- The objectives of this meeting, but is not limited to:

- to assess the proper implementation of the programme;
- to initiate further development of the programme;
- to discuss external communication to increase trust in NB's; and
- to elect new members to the Executive committee as needed.

Communication and Transparency

- On behalf of the executive committee, the task to store the documents and data from the assessments of TEAM-NB members under this CoC will be enacted by the managing Director, acting as secretariat of the executive committee.
- Conclusions of any appeal process will be published on the member's portion of TEAM-NB website in a standard format listing the conclusion of the assessment signed by the executive committee.
- A qualitative / semi-quantitative report will be published and regularly updates on the open portion of the website. Announcements on selected achieved progress in compliance confirmation and enforcement will be published in the news section to update all stakeholders on progress made.