# M7403 Customer Information - Certification according to Regulation (EU) 2017/745

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# Content

# 1. Purpose

The National Medical Device Conformity Assessment and Certification Ltd (hereinafter referred to as NEOEMKI or the certification body) is the legal successor of the National Institute of Pharmacy and Nutrition's Device Certification and Hospital Technology Directorate (formerly EMKI). The legal succession and the establishment of NEOEMKI are regulated by Government Decree No. 28/2015 (II. 25.) as amended by Government Decree No. 164/2020 (IV.30.).
The purpose of this document is to describe NEOEMKI's conformity assessment activities in accordance with Regulation (EU) 2017/745 (hereinafter referred to as MDR) for NEOEMKI's customers. NEOEMKI is a Notified Body with the NANDO (New Approach Notified and Designated Organizations) system identifier "1011" and a designation under the MDR.

# 2. Scope

This instruction applies to NEOEMKI's conformity assessment activities carried out under Regulation (EU) 2017/745, to NEOEMKI staff involved in those activities and to NEOEMKI's customers. It is an integral part of the General Terms and Conditions (M8903).

# 3. Definitions, acronyms

| Definitions, acronyms | Description |
|---|---|
| NCPHP (NNGYK) | National Center for Public Health and Pharmacy |
| NEOEMKI | National Medical Device Conformity Assessment and Certification Ltd. |
| MDR | Regulation (EU) 2017/745 |
| PSUR | Periodic Safety Update Report |
| PMS | Post-market surveillance |
| SSCP | Summary of Safety and Clinical Performance |
| SSP | Summary of Safety and Performance |
| ICT | Information and communication technology |
| Client | Medical device manufacturer (according to MDR Article 2.30) or its authorized representative (according to MDR Article 2.32). |
| incident | Means any malfunction or deterioration in the characteristics or performance of a device made available on the market, including use-error due to ergonomic features, as well as any inadequacy in the information supplied by the manufacturer and any undesirable side-effect. |
| serious incident | Means any incident that directly or indirectly led, might have led or might lead to any of the following: (a) the death of a patient, user or other person, (b) the temporary or permanent serious deterioration of a patient's, user's or other person's state of health, (c) a serious public health threat. |
| serious public health threat | Means an event which could result in imminent risk of death, serious deterioration in a person's state of health, or serious illness, that may require prompt remedial action, and that may cause significant morbidity or mortality in humans, or that is unusual or unexpected for the given place and time. |
| field safety corrective action (FSCA) | Means corrective action taken by a manufacturer for technical or medical reasons to prevent or reduce the risk of a serious incident in relation to a device made available on the market. |
| harmonised standard | Means a European standard as defined in point (1)(c) of Article 2 of Regulation (EU) No 1025/2012. |
| common specifications (CS) | Means a set of technical and/or clinical requirements, other than a standard, that provides a means of complying with the legal obligations applicable to a device, process or system. |

# 4. Responsibilities

| Person responsible | Task |
|---|---|
| Client | Carefully and thoroughly reading, understanding, acknowledging, and complying with the Customer Information. |
| NEOEMKI Managing Director | Ensuring that the Customer Information is distributed to Customers, and that it is available and up-to-date. |

# 5. Description of procedure

## 5.1 Principles

NEOEMKI places a high priority on building trust in its certification activities. The principles of trust building:

- impartiality
- competence
- responsibility
- openness
- confidentiality
- responding to complaints
- a risk-based approach.

### 5.1.1 Impartiality

NEOEMKI ensures the impartiality of its decisions and makes this visible in order to gain and maintain confidence in the certificates it issues.
NEOEMKI employees (own employees), contracted quality experts (auditors, product reviewers, clinical experts and case experts), subcontractors may participate in system certification and conformity assessment and supporting activities, provided that they have signed a declaration of independence, impartiality and confidentiality. Responsibility for the preparation and safekeeping of the declarations lies with the NEOEMKI Managing Director, who will verify the existence of the declaration before issuing the mandate for the certification activity.
All NEOEMKI staff, whether full-time, contracted or subcontracted, must report to the NEOEMKI Managing Director any changes that affect their impartiality and independence.
Regardless of the type of employment, all NEOEMKI staff must complete a risk management form for their personal activities, which is assessed by the Quality Manager and based on which any risk management measures are determined. The above form must be completed annually, and the risk assessment must also be carried out annually.
In the case of a mandate for a specific assessment activity, the quality experts also declare their independence and impartiality in relation to the manufacturer on the Assignment template.
In the case of conformity assessments under the MDR:
NEOEMKI personnel carrying out certification activities shall not participate in the assessment of products for which they have been directly involved in the design, manufacture, assembly, marketing, installation, use or maintenance, nor shall they participate in the certification of a management system for which they have provided advice (including specific instructions or suggested solutions for the design, implementation or maintenance of the management system) within three years or have carried out an internal audit for within three years. Our staff are committed to impartial judgement and integrity of the work carried out.
NEOEMKI, its management and its staff shall not provide, and shall not have provided in the last 3 years, any consultancy services to the manufacturer, its authorized representative, supplier or commercial competitor in relation to the EU design, construction, marketing or maintenance requirements of the products or processes under assessment.
NEOEMKI regularly assesses the risks to impartiality.

### 5.1.2 Competence

To maintain confidence in the certification activity and in the certification issued, NEOEMKI ensures the competence of its employees, certification and support staff.
NEOEMKI has sufficient staff with the necessary theoretical and practical training, technical knowledge and experience to carry out the certification tasks related to the nature, scope and extent of the work performed. Both the competence requirements and their fulfilment are regularly reviewed by NEOEMKI.

### 5.1.3 Responsibility

Following its internal procedures, NEOEMKI collects and documents sufficient objective evidence during the certification process and conformity assessment to make a responsible decision to grant certification.
Given that the certification procedure and conformity assessment are based on sample testing, NEOEMKI does not guarantee full compliance by granting certification. Regardless of NEOEMKI's decision, the client organization is responsible for the fulfilment of the relevant requirements and for maintaining the certificate after its issue during the certification procedure and cycle.
The NEOEMKI designated Certification Decision Maker is responsible for making a decision on compliance based on sufficient objective evidence. The project leader/assessment team leader will propose a decision in the submitted report as part of the documentation compiled: to issue, reject, maintain with or without amendment, maintain with amendment, suspend, revoke, or reinstate the certificate. Based on the assessment and certification documentation, the proposal and the findings of the assessment and certification staff, the decision-maker decides: to issue the certificate (if there is sufficient evidence of conformity), to reject it (if there is insufficient evidence of conformity), to maintain it with or without amendment, to maintain it with amendment, to suspend, to revoke or to reinstate it. If there is insufficient evidence to demonstrate compliance, they may either reject the application or return the complete assessment, certification dossier to the project manager for further evidence gathering.
NEOEMKI takes out appropriate liability insurance for its certification and conformity assessment activities. The scope and total financial value of the liability insurance shall be proportionate to the scale and geographical scope of NEOEMKI's activities and the risk profile of the quality management systems and devices it certifies. Liability insurance shall also cover cases where NEOEMKI is forced to revoke, limit, or suspend certificates.
NEOEMKI's liability for damages shall be confined to the limit of the liability insurance cover. The geographical scope of the policy does not cover the whole world, therefore NEOEMKI's certification activities do not cover the USA, Canada, Australia, and New Zealand.

### 5.1.4 Openness

NEOEMKI will make publicly available, on its website www.emki.hu, the relevant information on the certification and conformity assessment process it applies. Customers can provide their certification and conformity assessment data and requirements on forms and templates available on the NEOEMKI website. At its headquarters, NEOEMKI provides its partners with access to the operational regulations and up-to-date information on certified organizations and devices, which is also published on the website www.emki.hu.
On request, NEOEMKI will provide information on the certified status of products, the validity of certificates, the scope of validity and any restrictions. Information on certified quality management systems and products is published by NEOEMKI on Eudamed in accordance with the provisions of the MDR Regulation. In particular, the certificates, PSUR assessment and Summary of Safety and Clinical Performance (SSCP) or Summary of Safety and Performance (SSP).
NEOEMKI has data reporting obligations for conformity assessment procedures carried out under Regulation (EU) 2017/745 (e.g.: recording of information in the Eudamed system related to the certificate, recording of the results of the application review, summary of safety and performance, consultation procedure for clinical evaluation of devices in Class III or II.b, etc. , according to Article 57(1) sections (f), (g), (h) and (i) of the MDR) which it fully performs in accordance with the requirements of the relevant Regulation.

NEOEMKI is obliged to fulfil its duties and obligations under the legislation, to notify the supervisory body of certificates issued, modified or revoked and/or to record them in the relevant international database (e.g. Eudamed, CertSearch).

### 5.1.5 Confidentiality

NEOEMKI shall treat as confidential all information belonging to the customer, in particular the ownership, which the customer makes available to it during the certification and conformity assessment process. All NEOEMKI personnel, including subcontractors, involved in the certification, conformity assessment and supporting activities shall declare the confidentiality of the information and assume the legal consequences of any breach of this obligation.
During the assessment process, the designated assessment staff will also provide the client with a verbal declaration of confidentiality during the opening and closing meetings of the on-site assessment.
NEOEMKI will disclose customer data to third parties only with the prior written consent of the customer concerned. Exceptions to this rule are when data are requested by the authority responsible for the evaluation (the authority responsible for the notified body or the competent authority(ies) of the Member State(s) responsible for medical devices) or by the Commission, and when information may be provided to a body or person specified by law or other legislation.
Upon request of the client concerned, NEOEMKI will provide access to the materials related to the certification decision. In all cases, access will be logged.

### 5.1.6 Responsiveness to complaints

NEOEMKI will investigate and deal with all complaints that appear to be justified in an appropriate manner, taking care to balance openness and confidentiality, and will make reasonable efforts to resolve them. NEOEMKI has established a specific procedure for handling complaints and appeals (**E97** Handling events violating organizational integrity, complaints and appeals against a certification decision), which is published on its website (www.emki.hu), together with the form used in the procedures.
NEOEMKI keeps records of complaints and corrective actions related to certification and conformity assessment activities.
NEOEMKI evaluates complaints and appeals and their handling annually as part of the management review.

### 5.1.7 Risk-based approach

During its certification and conformity assessment activities, NEOEMKI continuously identifies, investigates, assesses and manages the risks associated with competent, consistent and impartial certification as described in the relevant procedures.

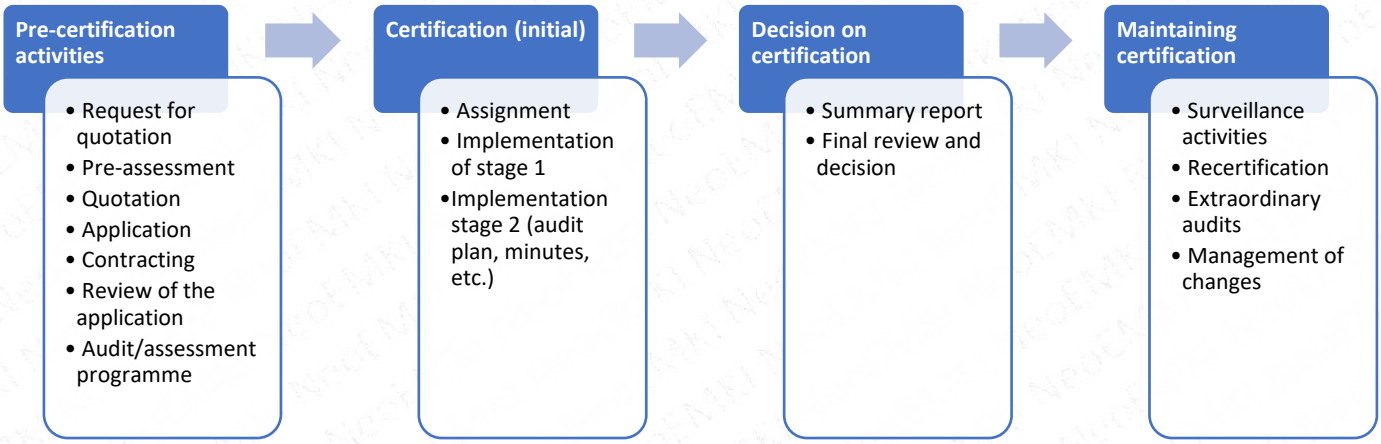
## 5.2 Documents to be submitted by the client

- The certification and conformity assessment procedures carried out by NEOEMKI can only be carried out based on uploaded documentation duly submitted by the customer in the appropriate form and manner. The submitted documents are official and form part of the certification and/or conformity assessment procedure and therefore both the uploader and NEOEMKI are responsible for them.
- NEOEMKI regulates the submission and management of customer documentation in the E98 Customer documentation management procedure. NEOEMKI will publish the customer-specific parts of the procedure on its website and may also make them known to the customer by other means (e.g. information e-mail, etc.).
- NEOEMKI accepts the necessary documents for the certification procedure only in Hungarian and/or English from the manufacturer or the authorized representative.

- In justified cases, NEOEMKI may require any information or data necessary to verify, check, certify conformity and maintain the validity of the certificate in relation to the chosen procedure.
- Customer documentation for certification and conformity assessment procedures can only be submitted to NEOEMKI via the upload link provided by NEOEMKI. NEOEMKI does not accept documentation by e-mail, file sharing or any other means!
- NEOEMKI is committed to keeping customer data secure. To achieve this and ensure the security, traceability and privacy of the data flow, each time a document is requested for upload, an upload link is emailed to the customer, allowing them to upload documents directly and securely to the NEOEMKI system library.
- For each upload, the client must attach a precise list of documents uploaded.

## 5.3 Description of the certification process

The certification process consists of 4 main stages as shown in the diagram below.




Asset regimes and/or asset pools within the scope of Article 22(4) of the MDR shall be treated by NEOEMKI as separate assets and shall be subject to all requirements according to their classification.

### 5.3.1 Pre-certification activities

#### 5.3.1.1 Request for quotation

In case a prospective or already certified client wishes to request a quotation for an evaluation or certification activity, they can do so by filling in the relevant data sheet (information sheet/quotation request form) which can be downloaded from the NEOEMKI website and sending it to the e-mail address cert@emki.hu.
If the enquiry is not received on the completed relevant form, or if the form is incomplete, the NEOEMKI administrator will contact the client in person (by telephone) or in writing (by e-mail) to clarify the missing data. If sufficient information is available to submit a quotation, NEOEMKI's administrators will file the incoming request for quotation.

#### 5.3.1.2 Pre-evaluation

Based on the received and duly filled in Request for Quotation forms, NEOEMKI will in all cases carry out a pre-evaluation according to its internal procedures. A contracting authority may carry out a pre-evaluation once the products, production sites, subcontractors and technologies have been clarified.

For incoming requests for quotation, NEOEMKI checks in Eudamed whether the manufacturer is registered and has a rejected application with another notified body for the same device.
During the pre-evaluation, NEOEMKI will check at least the following:

- The product(s) is (are) considered a medical device according to the applicable regulation.
- Whether the manufacturer's classification is correct.
- The certification route indicated by the manufacturer can be used.
- NEOEMKI's designation is valid for the product and route.
- Whether resources are available at NEOEMKI.
- There is no rejected application with another notified body for the same device.
- Potential risks, with particular attention to independence and impartiality.

NEOEMKI will keep a record of all pre-evaluations carried out.
In all cases, NEOEMKI will inform the client of the result of the pre-evaluation, which is the responsibility of the Managing Director.

#### 5.3.1.3 Quotation

In the event that the results of the pre-evaluation allow a quotation to be issued, the Managing Director, if necessary with the involvement of the administrators, will prepare a quotation. The completed quotation may be sent to the client only after approval by the Managing Director.

No separate quotation will be made for the issue of an expert opinion under Article 117 of the MDR. The draft contract, including the quotation, is drawn up by the Managing Director based on the relevant template.

NEOEMKI shall attach the following to the MDR quotation in all cases:

- General Terms and Conditions
- Application form (MDR)
- List of devices (To be attached to the application form in all cases.)

The quotation will be prepared for the entire certification cycle based on the pre-evaluation carried out, the list of standardized fees and the fee calculation for contracts as described in the instructions.
The Application form template contains the documents to be submitted with the application, to be filled in by the client.

#### 5.3.1.4 Application, contracting

In the event that the client does not accept NEOMKI's quotation, the certification/conformity assessment procedure will not be requested.
In case the customer accepts NEOEMKI's quotation, they will have to apply for the certification/conformity assessment procedure. NEOEMKI will consider as an application the documents completed and submitted by the client marked with an X in the table below:

| Territory | NEOEMKI quote accepted by the client | **S8902** Application for conformity assessment procedure under MDR Regulation + submission of related documentation |
|---|---|---|
| Conformity assessment under MDR | **X** | **X** |
| Preparation of an expert opinion under Article 117 MDR | **X** | |

The application may only be submitted in writing to NEOEMKI by the manufacturer of the medical device covered by the application or his authorized representative. The template for submitting the application is available on the NEOEMKI website.
As soon as possible after the application has been submitted, the administrators will send the certification contract signed by the NEOEMKI Managing Director to the client for acceptance. The General Terms and Conditions will always be annexed to the certification contract. In the case of an opinion issued under Article 117 of the MDR, the contract will be sent to the client when the quotation is issued.
Only a contract signed by both parties can be legally enforceable, and it is the responsibility of the administrators to follow up the signing and return of the contract.
In the case of conformity assessments under the MDR, the certification contract will include the following: the conformity assessment activity will only be carried out by NEOEMKI if the application submitted by the customer meets the conditions for acceptance of the application during the review in accordance with Regulation (EU) 2017/745 and, if relevant, MDCG 2019-3.

The client is required to pay the application review fee, the current amount of which is available on the NEOEMKI website, within 5 days of the submission of the application. NEOEMKI will only start the review of the application after the payment of the application review fee. The application review fee shall be included in the certification fee, provided that the application is complete and complies with Annex IX, point 2.1 of the MDR.
Upon receipt of the application, the certification body will issue a fee request for the application review fee, which will be sent to the client by e-mail. The evaluation of the application can start after the payment of the review fee and the receipt of all required documents.

#### 5.3.1.5 Application review

In all cases, applications received must be reviewed in accordance with the relevant NEOEMKI internal procedures within 60 days of submission and documented on the relevant NEOEMKI template.
Requirements for the review of applications for conformity assessment under the MDR:

- The application is reviewed by an auditor, product reviewer, internal clinician or NEOEMKI internal staff member with decision-making competence by completing the Application Evaluation Report template.
- During the review of the application, the following will be reviewed:
  - the application is submitted by the manufacturer or authorized representative of the medical device covered by the application,
  - the completeness of the application with regard to the requirements of the conformity assessment procedure referred to in the relevant Annex under which approval is sought,
  - checking whether the products covered by the applications are considered devices and which class(es) they belong to,
  - determining whether the conformity assessment procedures chosen by the applicant are applicable to the device in question under the Regulation,
  - NEOEMKI's authority to assess the application based on its designation and the availability of sufficient and appropriate resources.

If the review of the MDR application concludes that,

- the data do not match the data in the request for a quotation, the discrepancy should be clarified with the applicant, and if necessary, a new request for a quotation should be requested or the request should be rejected.
- additional information is required, a request for supplementary information must be made within 30 days.

In the case of a request, the client may be given the opportunity to make up for the deficiency once.
If the request is rejected or withdrawn, the Certification Office Manager must record it in the Eudamed system, while informing the client.

NEOEMKI shall in all cases notify the applicant of the result of the application review by sending a documented report on the application review within 30 days of the completion of the assessment, which is the responsibility of the Certification Office Manager.

### 5.3.1.6 Certification cycle planning

NEOEMKI prepares a program for the entire certification cycle for certification, conformity assessment activities and records it on the relevant NEOEMKI internal template.
In the case of an opinion under Article 117 of the MDR, the nature of the assessment activity (one-time) does not require the planning of a certification cycle (certification program).
NEOEMKI will take into account the size of the client organization, the scope and complexity of the management system, the products, the processes and the level of effectiveness of the management system and the results of the procedures previously carried out when designing the program and any subsequent modifications. In the case of a client with multiple shifts, NEOEMKI will also take into account the activities during the shift when designing the program. In the program, NEOEMKI shall clearly define the assessment activities that are necessary to demonstrate that the client's management system and/or products meet the certification requirements set out in the relevant legislation, standards and other governing documents.
In the case of conformity assessment under the MDR, NEOEMKI ensures the rotation of auditors in the program, in particular the lead auditor: a lead auditor may not lead and perform an audit at the same manufacturer for more than 3 consecutive years. NEOEMKI will document any deviation from this and assess the risks involved.
The program will include the sites to be audited and the technical documentation to be assessed, and, where relevant, their sampling.
The first certification cycle always starts with the certification decision. Subsequent certification cycles start with the recertification decision. The certification cycle for the MDR conformity assessment area is five years.
The initial certification process always consists of two stages:

| Stage 1 | Stage 2 |
|---|---|
| preliminary review of quality management documentation | on-site audit |
| on-site visit, if necessary | |
| review of technical documentation according to the sampling plan + if necessary, conduct of relevant additional procedures (according to Annex IX, Chapter 5 of the MDR) | |

**In the case of surveillance and recertification procedures, stage 1 is only necessary if justified by changes indicated by the client or detected by NEOEMKI.**
NEOEMKI carries out surveillance audits once every 12 months for the MDR conformity assessment area.
The date of the first surveillance audit following the initial certification shall not be later than 12 months after the certification decision has been taken.
If the prescribed deadline cannot be met for reasons attributable to the client, the valid certificate will be temporarily suspended by NEOEMKI for a maximum period of 6 months. Audits that can be carried out within this period will be treated by NEOEMKI as extraordinary audits. If the 6-month period is exceeded, the certificate will be revoked. If the time limit is exceeded due to NEOEMKI's fault, the above procedure shall be followed so that the client does not suffer any disadvantage as a result.
In all cases, the recertification process must be designed to be completed in sufficient time to allow timely renewal of the certificate before its expiry date.
NEOEMKI will review the program after each evaluation activity when changes are reported or detected, as well as prior to surveillance and recertification audits, and will make documented changes where necessary and justified.

### 5.3.2 Certification procedure (initial)

The initial certification process always consists of two stages. For surveillance and recertification procedures, stage 1 is only necessary if justified by changes indicated by the client or detected by NEOEMKI.

NEOEMKI may identify nonconformities during both the Stage 1 and Stage 2 reviews, either for the quality management system or for the technical documentation reviewed. NEOEMKI will record all nonconformities identified in a nonconformity report and provide it to the customer. The handover shall take place within the framework of the final meeting of the audit in the case of nonconformities detected during the on-site audit, and within 7 days of the recording of the nonconformities not detected on-site. The client's representative shall have the right to comment in writing on the nonconformity reports and, where justified, to express disagreement or objection to the contents of the reports. These comments and objections, if any, shall not affect the conclusion of the on-site audit, technical documentation evaluation and shall be investigated in any case, if necessary, in accordance with NEOEMKI's complaints handling procedure.
NEOEMKI classifies detected nonconformity into two categories:

- Major nonconformity: systemic failure (complete absence of standard and/or legal requirement in documents; repeated, systematic deviation) and non-compliance with regulations (MDR and/or IVDR).
- Minor nonconformity: minor nonconformities are those that occur in isolated, sporadic cases, do not compromise safety or can be corrected quickly.

If nonconformity is identified during the procedure, the client must submit a corrective and preventive action plan (CAPA plan) to the certification body within 15 days. The CAPA plan shall include at least the following: method of root cause determination, root causes, actions to be taken with responsibilities and timeframes. The client shall submit to the certification body the documents justifying the correction of the nonconformities by the deadline agreed in the corrective and preventive action plan accepted by the certification body. In the absence of corrective action, the procedure shall be closed at the end of the period foreseen in the preventive action plan.

In the case of minor nonconformity, it is sufficient for the client organization to submit the necessary corrective and preventive action plan to NEOEMKI, and their implementation will be verified during the next on-site audit.

In the case of major nonconformity, the implementation should be verified by checking the revised documentation or during a follow-up audit.

In the case of an initial procedure, 180 days (150 days for rectification by the customer + 30 days for verification by NEOEMKI) are allowed for the rectification of detected nonconformities, while in the case of a surveillance, recertification or special procedure, 90 days (60 days for rectification by the customer + 30 days for verification by NEOEMKI) are allowed from the date of detection.

#### 5.3.2.1 Assignment

NEOEMKI appoints an evaluation team and a decision-maker for the implementation of each procedure - initial, surveillance, recertification, extraordinary and if necessary, related to change management- on the basis of the valid certification program and the relevant competence matrix, taking into account the risks of independence and impartiality. The composition of the team and the appointment of the members and the decision-maker shall be carried out by the person authorized to appoint them, taking into account the product scope and ensuring the necessary preparation, using the relevant internal NEOEMKI procedures and the relevant annexes and templates.
Persons licensed to carry out assessment activities under the MDR shall comply with the requirements set out in Annex VII, point 3.2.2 of the MDR.
In all cases, the assessment team will be assembled so that together they have the necessary competence to certify the products and the quality management system. Only persons with duly certified competence as listed in the valid

competence matrix may be appointed (evaluation team, decision-maker). If only one lead auditor is appointed, they must also be qualified to carry out the tasks of a team leader for the task in question.
The evaluation team consists of the team leader/project leader, lead auditor, auditors, product reviewers, internal clinician and clinical experts. The team leader/project leader must be an internal staff capable of checking the relevance and validity of external expert opinions.
For the preparation of an expert opinion according to MDR 117, at least one product reviewer who prepares the opinion and one product reviewer who verifies the prepared opinion shall be appointed during the designation. Where appropriate, a clinical expert or ad hoc expert may be involved in the evaluation.
Candidates who are auditors, product reviewers or internal clinicians may be assigned as participants in the evaluation team, in which case an auditor, product reviewer or internal clinician should be assigned as a mentor. The mentor should be ready to take on the task and should have the ultimate responsibility for the candidate's activities and findings.
When NEOEMKI employs observers, translators and interpreters, it shall select them in such a way as not to unduly influence the proceedings and to ensure the impartiality of the evaluation and confidentiality.
During the designation process, NEOEMKI checks (on www.clinicaltrials.gov.us and in the Eudamed database) whether the clinical expert has been involved in a clinical evaluation of a device.
The decision-maker and the other members of the evaluation team must not be related and the decision-maker must not participate in the evaluation process. The person who makes the designation for a project cannot be the final reviewer and decision-maker for that project.
The evaluation team may also include ad hoc experts, in particular when examining clinical evaluations and when specific expertise is needed for a particular device.
In making the designation (determining the number and composition of the evaluation team), NEOEMKI will take into account:

- the purpose, scope and criteria of the evaluation;
- the total and partial time needed for the assessment, including the time needed for the on-site audit;
- the type and nature of the evaluation procedure,
- the collective preparedness of the evaluation team to achieve the objectives of the evaluation;
- the evaluation requirements (including any applicable legal, regulatory and contractual requirements);
- the range of products and the professional requirements needed to carry out the task,
- MDR codes,
- specific requirements,
- any potential conflict of interest,
- language and culture,
- whether the members of the evaluation team have previously audited the client's management system and evaluated the assets of the product range,
- the rotation of auditors, in particular the lead auditor.

In the case of initial and recertification procedures, NEOEMKI will designate the evaluation team separately for Stage 1 and Stage 2 of the procedure. If the group members are not the same in the two phases, the new member is required to read through the Stage 1 records for the client, ensuring that all Stage 1 information is provided.
The composition of the evaluation team and the appointment of its members for the whole cycle will be documented in the certification program. For a given evaluation project/procedure, the designation shall be recorded on a template in the relevant annex to the assignment.
The designation is made in writing and sent by e-mail by the administrator to the interested parties. Acceptance of the designation also means that there is no risk of impartiality or conflict of interest on the part of the person designated in relation to the task to be performed. By signing the designation, the staff member concerned certifies that there is no risk of impartiality or conflict of interest in relation to the task to be performed.

The administrator shall inform the customer in writing of the designated members of the team involved in the evaluation activity. In the event that the client objects to one or more of the designated members within 5 working days, the nominator will examine the validity of the objection and, if possible, nominate another person. If it is not possible to change the designation for organizational or other reasons, or if this would result in a change in the contractually agreed time for the evaluation, the client shall be consulted on the changes and, as a last resort, the contract shall be terminated.
If the client does not respond in writing within 5 working days to the composition of the evaluation team, the composition of the team will be considered accepted by NEOEMKI.
The designation becomes final after the acceptance of the persons by the client. If, after the designation has been finalized, the composition of the team needs to be changed, the relevant steps of the designation process shall be repeated, and the program shall be updated with justification.
After agreement within the group, the head of the evaluation team (project leader) allocates the specific tasks related to auditing and evaluating different processes, functions, sites, areas or activities to the members of the team.

#### 5.3.2.2 Stage 1

The objectives of Stage 1:

- obtaining the necessary information on the scope of the quality management system and the products (e.g. sites, processes)
- review of client management system documentation, management review and evaluation of internal audits (planning, implementation),
- in the case of conformity assessment areas, review of the technical documentation of the medical devices concerned based on the program, and, if necessary, the conduct of the relevant additional procedures (according to Annex IX, Chapter 5 of the MDR),
- assess the circumstances at the client's site and conduct discussions with the client's staff to assess the client's readiness for Stage 2,
- reviewing the situation at the client's premises to get an idea of how well they understand the requirements of the relevant legislation and standards,
- reviewing resources for Stage 2 and agreeing with the client the details of Stage 2,
- gathering and interpreting the information needed to plan Stage 2

If necessary to achieve the objectives set out above, at least part of Stage 1 may be carried out at the client's premises.
The head of the evaluation team (project leader) will prepare a report on the findings of Stage 1 using the relevant annexes and templates.
The documented conclusions of the first phase on the achievement of the objectives of Stage 1 and the readiness for Stage 2 of the procedure will be communicated to the client by NEOEMKI in a documented manner, including the identification of any areas of concern that may be considered nonconformity in the second phase of the audit.
In the case of an opinion under Article 117 of the MDR, only Stage 1 is required, which concerns the assessment of the product documentation submitted by the client.
After the completion of Stage 1 of the procedure, NEOEMKI will review the certification program for the problems found in Stage 1. If justified, the client shall be given adequate time to resolve the problems, taking into account the procedural deadlines. In the event of a change with a significant impact on the management system or products, the evaluation team shall in any case consider re-conducting all or part of Stage 1. The client shall be informed by the team leader/project manager if the results of Stage 1 may lead to the postponement or cancellation of Stage 2.

The certification body sends the report of Stage 1 to the client within 30 days after the completion of Stage 1, but no later than 10 days before the on-site audit. The report shall contain the results of the assessment, both for the quality management system and for the technical documentation reviewed, and the nonconformities found. The results of Stage 1, and in particular any nonconformities, may lead to the postponement or cancellation of Stage 2.

If a major nonconformity is detected during Stage 1, either in the quality management system or in the technical documentation reviewed, the client must correct the nonconformity within the time limit set and in any case before the on-site visit. Until these corrections have been verified, the on-site audit cannot take place, and therefore no appointment can be made for it.

In the case of an integrated quality management system, it should be verified that the level of integration, including the level of integration of documents, the elements and responsibilities of the management system (as per IAF MD 11 Annex 2) and the ability to perform an integrated audit have not changed compared to the previous evaluation. If there has been a change, the necessary changes should be implemented in a documented manner.
Stage 2 of the procedure cannot be started if the following deficiencies are found:

- the customer's quality management system is not ready to carry out Stage 2;
- the client does not have the resources to carry out the activities;
- the client does not demonstrate understanding of the requirements and fulfilment of the key criteria;
- it can be presumed based on the technical/management documentation that the customer does not have the evidence and procedures to meet the relevant essential requirements.

#### 5.3.2.3 Stage 2

Stage 2 of the evaluation process is carried out by NEOEMKI at the customer's site(s) and critical subcontractors. On-site inspections at subcontractors are also necessary if processes that significantly affect the performance or safety of the device(s), e.g. relevant design, manufacturing or testing/inspection steps, are not performed at the client's site.
In the case of an opinion under Article 117 of the MDR, Stage 2 is not carried out. The reports produced in Stage 1 are sent to all staff involved in Stage 2. The on-site audit process is described in detail in NEOEMKI's internal procedures. The deadline for the start of Stage 2 is 30 days after the end of Stage 1.
NEOEMKI will communicate the dates and duration of the audit to the client in a timely manner. NEOEMKI shall also take the client's requests into account when agreeing the date. The tasks to be performed during the on-site audit shall be planned in the audit plan. The audit plan shall contain a description and schedule of activities and measures to be taken in connection with a given on-site audit, as defined in the certification program. After the audit date has been agreed, the audit plan shall be sent to the client at least one week before the on-site audit. The audit plan should be finalized with the client at the opening meeting of the on-site audit. NEOEMKI may deviate from the audit plan if necessary, but such deviations must be documented and justified in the audit report. It is the responsibility of the evaluation team leader/lead auditor to ensure effective communication within the evaluation team.
In the case of a combined audit, the audit plan should cover all areas and activities applicable to the audit scope as defined by each management system standard and applicable legislation. If the use of ICT is planned during the audit, it should be recorded in the audit plan, together with its extent.

During the audit, the audit team systematically examines the implementation, operation and documentation of the quality management system. The client shall ensure that the persons necessary for carrying out the audit are available to the auditors, that the audit team members have access to the documents to be examined, have access to the necessary operational areas and support the auditors in their work to ensure that the audit is carried out in a satisfactory manner. The information subject to audit includes design, development, manufacturing and quality control activities, results of internal audits, management reviews, complaints and their handling, as well as incident reporting, corrective actions and other regulatory reporting requirements. The audit also includes verification that the client is complying with the regulatory reporting obligations.

At the final meeting of the audit, NEOEMKI will state whether the purpose of the audit has been met and record the conclusions of the audit, in particular any nonconformities detected, and will prepare and submit a report to the client. Any nonconformities detected during the audit must be recorded in the nonconformity report and handed over to the

client. The conclusions of the audit shall be recorded by the evaluation team in a complete, concise, and clear audit report, which shall be made available to the client within 30 days of the audit's completion.
If the audit objective has not been met, NEOEMKI will indicate this to the client in a documented manner at the closing meeting and will draw the client's attention to the fact that a follow-up audit may be necessary in this case, in addition to reviewing and amending the certification program for the cycle.
In the case of a conformity assessment area, if the client is unable to provide the technical documentation during the on-site audit and/or it is found that there is a discrepancy between the data in the technical documentation and what is found on site, this shall be documented as a major nonconformity.

#### 5.3.2.4 Conclusions, information for the certification decision

Both the quality management system auditors and the reviewers of the technical documentation of the devices (product reviewers, internal clinician, clinical experts, ad hoc experts if necessary) work in teams to evaluate and record the information gathered during the process. The evaluation team analyses all the information and evidence gathered during Stages 1 and 2 of the procedure, reviews the audit and assessment findings and reaches conclusions on the procedure.
At a minimum, the evaluation team will provide the final reviewer and decision maker with the following for the certification decision:

- the reports produced during the evaluation process;
- comments on any nonconformities that may have occurred, as well as notes confirming the corrections and corrective actions taken by the client;
- confirmation of the information submitted and used to review the application;
- a recommendation to issue or refuse, modify, suspend, revoke or reinstate certification, together with any conditions or comments.

The factual data and the decision proposal necessary to make a certification decision are recorded by the evaluation team in a report and accompanying documents, and then forwarded to the decision-maker.
In the case of an opinion under Article 117 of the MDR, a narrative report is not required because the evaluator has recorded his conclusions in the opinion template.

### 5.3.3 Certification decision

Certification may only be issued, refused, revoked, suspended, reinstated or amended on the basis of a certification decision taken by the competent decision-maker(s) on the basis of the valid competence matrices and recorded in the certification decision record.
Only an internal NEOEMKI staff member can make a decision. A person who is involved in a given (specific) conformity assessment procedure as a nominator, auditor, lead auditor, product reviewer, clinical expert, ad hoc expert, or is related to the foregoing, or whose independence or impartiality is not certified, may not participate in certification decision-making.
The certification decision-maker makes their decision on certification on the basis of an evaluation of the findings and conclusions of the assessment procedure and any other relevant information.
The NEOEMKI conformity assessment procedure process is regulated to ensure that the certification procedure covers all the requirements necessary for a certification decision.
NEOEMKI regulates in detail the activities of issuing, suspending, revoking, reinstating, amending and managing conformity assessment certificates issued by NEOEMKI in a separate internal procedure.
In the case of an opinion under Article 117 of the MDR, no certification decision is taken and no certificate is issued.
The completed evaluation shall, in all cases, be verified and, if appropriate, approved by the person with the appropriate competence designated under the relevant mandate and recorded on the evaluation template.

NEOEMKI shall inform the customer in writing of the certification decision within 10 days of the decision being made. If the certification is subject to restrictions, NEOEMKI shall clearly state this on the certificate. Certificates shall be valid for a maximum of five years.
NEOEMKI issues certificates in Hungarian and/or English only.
If NEOEMKI refuses to issue a certificate, the manufacturer may appeal in writing within four weeks. Objections or appeals will be investigated in accordance with the relevant NEOEMKI procedure (E97 Handling events violating organizational integrity, complaints and appeals against a certification decision).
All certificates issued, as well as applications for which a negative certification decision has been taken, are reported by NEOEMKI to the Eudamed database. If the manufacturer withdraws its application for certification or terminates the certification contract, NEOEMKI will review the documents related to the evaluations carried out until then and will also report the withdrawn application to Eudamed.
NEOEMKI has data reporting obligations for conformity assessment procedures carried out under Regulation (EU) 2017/745 (e.g.: recording of information related to the certificate in the Eudamed system, recording of the results of the application review, summary of safety and performance, consultation procedure for clinical evaluation of devices in Class III or II.b, etc., according to Article 57(1)(f), (g), (h) and (i) of the MDR), which it fully performs in accordance with the requirements of the relevant Regulation.

### 5.3.4 Maintaining certification

In the case of an expert opinion under Article 117 of the MDR, maintaining certified status is not a relevant activity due to the nature of the activity and no certificate will be issued.

#### 5.3.4.1 Surveillance activities

NEOMKI carries out surveillance activities to determine whether the client applies the approved quality management system and post-market surveillance plan for the device. If the client requests a change to the date of the first surveillance audit that may cause a change in the 12-month deadline for the issuance of the initial certificate, NEOEMKI shall also inform the customer in writing and record the result of the date agreement.
NEOEMKI has designed its monitoring activities to:

- regularly monitor the typical activities and functions within the scope of the certified management system;
- take into account changes related to the certified client and its management system and product range.

The surveillance procedure can be carried out in one (stage 2 only - on-site surveillance audit) or two stages (stages 1 and 2). Stage 1 is always required when reviewing the technical documentation of devices not yet assessed during the assessment cycle and/or in the case of a significant change to a device and/or an approved quality management system, or in the case of an exceptional occurrence. The evaluation team leader (project leader) shall prepare a report on the findings of Stage 1 and inform the client of the outcome.
During the monitoring procedure

- the information described in point 5.3.1.6 of the Customer Information shall be reviewed and, if necessary, amended,
- the procedures described in sections 5.3.2 and 5.3.3 of the Customer Information must be carried out.

Monitoring activities include

- on-site (surveillance, extraordinary) audits;
  Surveillance audits are on-site audits, but do not necessarily cover the whole system, but rather the areas identified in the certification program.
  At a minimum, the following will be assessed: design, development, manufacturing and quality control activities, internal audits, management review, management of complaints and incidents, effectiveness of the management system in achieving product compliance, continuous monitoring of operations, continuous improvement activities.

- reviewing the treatment of nonconformities identified in the previous procedure,
- the use of marks and/or other references to the certified status,
- unannounced audits (as per Annex IX, point 3.4 of the MDR, at least once every 5 years),
    - Both the manufacturer and its subcontractors must ensure that unannounced visits are carried out on their premises. Refusal to do so or obstruction of an unannounced visit is a serious breach of the certification rules and will result in immediate suspension of certification.
    - During unannounced audits, NEOEMKI will examine a suitable sample of the finished devices or from the manufacturing process and/or may take samples of devices in circulation to determine whether the manufactured device complies with the technical documentation.
    - NEOEMKI will, if necessary, have the appropriate tests for the device carried out by an external laboratory or will invite the customer/manufacturer to carry out such tests. The costs of tests, test samples, transport and disposal shall be borne by the customer. If test samples can only be obtained from the market, the cost of obtaining them shall also be borne by the customer.
    - If NEOEMKI finds that samples taken from devices manufactured or placed on the market do not conform to the technical documentation, it must suspend or revoke the relevant certificate or impose restrictions on it.
- For products:
    - evaluation of additional technical file(s) based on the sampling plan, but at least 1 technical file,
    - reviewing the up-to-dateness of technical documentation,
    - reviewing the technical documentation in case of changes
    - evaluation of PSUR reports;
    - evaluation of PMS and PMCF activities;
    - the evaluation of vigilance;
    - internal clinical research;
    - laboratory testing of devices taken from production, warehouse or market.
- in the case of certificates issued with special conditions, an examination of whether the client fulfils the conditions imposed on him in the context of certification decisions, including, for example, a review of the clinical evaluation;
- review of changes, including tracking changes in legislation, uniform specifications and standards applicable to the product, and implementation of notified and approved changes,
- other supervisory activities. For example: questions asked to the manufacturer about aspects of certification; review of public documents relating to the manufacturer's activities (e.g. propaganda materials, website).

NEOEMKI maintains certification status based on evidence that the customer continues to comply with the requirements of the applicable legislation, Common Specifications (CS), and relevant standards (in the case of MDR: MDCG 2021-5), guidelines, specifications. If, in the course of surveillance activities, the evaluation team finds that samples of manufactured devices or samples taken from the market do not conform to the specifications specified in the technical documentation or the approved design and/or that the approved quality management system is not functioning properly, the relevant certificate shall be suspended or revoked, or restrictions shall be imposed.

#### 5.3.4.2 Recertification

The recertification procedure should be designed so that decisions can be taken before the certificate expires, taking into account the time needed for any corrections. It should be carried out by assessing the continued compliance with all the requirements of the management system and the assets involved.
The purpose of the recertification audit is to confirm that the management system

- as a whole is in constant compliance with the requirements;
- works effectively;
- remains appropriate and applicable to the scope of certification,

and the products covered by the certification

- continue to meet the relevant requirements;
- they correspond to what was expected by the state of art at the time.

To renew, the customer must indicate to NEOEMKI that he wishes to renew the certification cycle and request a quote at least 18 months before the expiry of the certificate. If the quote for recertification is accepted, the application, together with the complete documentation, must be submitted no later than 12 months before the expiry of the certificate and a new contract for the new certification cycle must be concluded.

The process of the recertification procedure (except for Stage 1) is the same as the initial procedure. During renewal, a full review of both the product and the quality management system will be carried out, and this will be extended by NEOEMKI to include a review of the reports of previous surveillance procedures. As a first step in the recertification process, an certification program for the new cycle will need to be developed in accordance with our relevant regulations.

In the case of the conformity assessment area, a full assessment of the technical documentation(s) selected on the basis of the sampling plan and, if necessary, the conduct of consultation procedures are an integral part of the recertification audit.

In the recertification procedure, Stage 1 must be carried out if

- there have been significant changes in the management system or in the products or range of products (e.g. introduction of a new product group; substantial modification of procedures, processes or technology; substantial change in the organizational structure);
- or the conditions under which the management system operates (for example, changes in legislation or uniform standards);
- the technical file is assessed beforehand.

During the on-site audit of the recertification audit, NEOEMKI confirms the following:

- the effectiveness of the management system as a whole in the light of internal and external changes, and its continuing suitability and applicability in the field of certification;
- a demonstrated commitment to maintaining and improving the effectiveness of the management system to ensure product compliance;
- the functioning of the management system contributes to the achievement of the organization’s policies and objectives.

If nonconformities or gaps in the evidence of compliance are found during the recertification process, the evaluation team will set deadlines for correction and corrective action to be implemented before the certification expires.

The decision to renew certification is based on the following information:

- the results of the recertification process;
- the results of audits of the manufacturer's quality management system carried out during the certification cycle;
- comments and complaints from users of certified products,
- the result of the review of the technical file(s).

The recertification process, including the review of the technical documentation(s), **must be successfully completed before the expiry** of the current certificate in order to maintain the certified status of the equipment. In this case, the expiry date of the new certification may be based on the expiry date of the existing certification.

If the recertification process cannot be completed within six months of the expiry of the previous certification, the renewal of the certificate will no longer be approved. In this case, the recertification procedure will be closed by NEOEMKI with an unsatisfactory result and the client may initiate an initial procedure, which shall be carried out starting from point 5.3.1 of the Customer Information.

#### 5.3.4.3 Special procedures

Extraordinary evaluation activities (e.g.: extension of scope, investigation of a complaint, etc.) are planned by NEOEMKI by implementing the relevant points of chapter 5.3.1 of the Customer Information and are carried out taking into account the provisions of point 5.3.2.
NEOEMKI will take into account certificates issued by other accredited or notified bodies and is ready to transpose them upon request of the client. Transposition in case of conformity assessment is done according to Article 58 of the MDR.
Only the transfer of certificates is possible

- for which the scope of the certified product falls within the scope of the accredited or designation areas of NEOEMKI;
- for which the evaluation module (route) is one of the modules that can be selected in the specific NEOEMKI designation area;
- where the certification of the client requesting the transfer is valid for the duration and scope of the certification.

NEOEMKI does not undertake the transfer of certificates that have been revoked, suspended or threatened with suspension.
Activities of transposition:

- documentation review
- communication with the issuing organization (if possible)
- communication with the competent authority (if necessary)
- decision to accept the transfer request
- conducting a full assessment of at least one technical file
- on-site audit at the customer's premises
- the issue of a re-issued certificate with the same validity and scope as the one originally issued.

# 6 Additional requirements related to certification

## 6.1 Summary of safety and clinical performance (SSCP)

The client must provide a clear, publicly available summary report to the target user, and where appropriate the patient, on the safety and clinical performance (SSCP) of Class III devices and implantable devices, according to Article 32 of the MDR, except for custom-made devices and devices intended for clinical investigation. The SSCP shall be made publicly available through Eudamed.
The draft SSCP must be included in the client's documentation to be submitted to NEOEMKI with the application. NEOEMKI shall validate these summaries by verifying the existence of the necessary documents and confirming compliance with the relevant parts of the technical documentation. The validation shall be carried out by NEOEMKI based on the criteria listed in Article 32(2) of the MDR.
After validation, NEOEMKI uploads the summary to the Eudamed database and notifies the client within 10 days of upload.

## 6.2 Periodic safety update report (PSUR)

Manufacturers of devices in class IIa, IIb and III shall prepare a periodic safety update report (PSUR) for each device and, where applicable, for each category or group of devices, summarizing the results of the post-market data analysis and conclusions of the post-market surveillance data collected in the framework of the post-market surveillance plan

referred to in Article 84 of the MDR and describing the preventive and corrective actions taken and the justification for them. This report shall include the following for the whole life cycle of the device concerned:

- conclusions to be used in the risk-benefit assessment;
- the main findings of the post-marketing clinical follow-up; and
- the quantity of the asset sold, the estimated size of the group using the asset and, where possible, the frequency of use of the asset.

Manufacturers of Class IIb and Class III devices must update the report at least annually. The periodic safety update report shall be included in the technical documentation specified in Annexes II and III of the MDR, except for custom-made devices. Manufacturers of Class IIa devices shall update the periodic safety update report as necessary, but at least every two years. The periodic safety update report shall be included in the technical documentation specified in Annexes II and III of the MDR, except for custom-made devices. For custom-made devices, the periodic safety update report shall be part of the documentation referred to in point 2 of Annex XIII to the MDR.
For Class III or implantable devices, manufacturers must submit their safety reports to NEOEMKI via the electronic system (Eudamed) referred to in Article 92 of the MDR. NEOEMKI shall examine the report and record its assessment, together with details of the measures taken, in the Eudamed system. NEOEMKI shall make these periodic safety reports and NEOEMKI's assessment available to the competent authorities in Eudamed.
In the case of devices other than those referred to in Article 86(2) of the MDR, manufacturers shall make periodic safety update reports available to NEOEMKI and, upon request, to the competent authorities.

## 6.3 Products without an intended medical purpose

A list of product groups with no medical use is given in Annex XVI of the MDR. NEOEMKI will carry out conformity assessment activities for these devices only if the uniform specifications for the products are published, compliance with which is mandatory. For each product group, the application of risk management and clinical safety evaluation must be addressed. Devices belonging to these product groups should also be classified according to the MDR rules and their conformity assessment procedure should be chosen. The procedure is essentially identical to the conformity assessment procedure for other devices with similar uses and risks covered by the MDR.

## 6.4 Specific additional procedures (Consultation procedures)

For a certain range of devices to be certified, additional (consultation) procedures are required to be carried out by NEOEMKI during the certification procedure according to Annex IX, Chapter II, point 5 of the MDR.
**Principle:**

- Any consultation procedure may only be started after a review of the technical documentation carried out by NEOEMKI. At this stage, the record of the review of the technical file shall be marked "pending" in relation to the outcome of the consultation.
- For all consultation procedures, the consulting authority must be notified of the NEOEMKI certification decision.

### 6.4.1 Assessment procedure for certain class III. and class II.b devices

The procedure related to Annex IX, point 5.1 of the MDR must be carried out by NEOEMKI:
for implantable devices in Class III and active devices for the administration and/or removal of medicinal products from the body in Class IIb as referred to in Annex VIII, point 6.4 (Rule 12) of the MDR.
For devices that have already been certified under the MDD, consultation is not required (under MDR Article 54.2 and MDCG 2019-3 Rev.1) in the case the manufacturer has only made changes to meet the MDR requirements.

For these devices, NEOEMKI will forward to the Commission the report of the clinical evaluation audit of the device and the manufacturer's documentation related to the clinical evaluation.
The Commission forwards these documents to the relevant Expert panels (Article 106 MDR).

The Expert panels may decide not to provide a scientific opinion, in which case it will notify NEOEMKI of its decision no later than 21 days after receipt of the documents from the Commission. NEOEMKI will then continue the certification procedure.
If it decides to give an opinion, it will do so within 60 days of receipt of the documents from the Commission. If the Expert panels considers that it cannot reach a conclusion based on the information provided, it shall record this in the scientific opinion. If no scientific opinion is issued within 60 days, NEOEMKI shall continue the certification procedure for the device.

NEOEMKI shall take due account of the views expressed in the expert opinion of the Expert panels. Where the expert committee concludes that the amount of clinical evidence is insufficient or the evidence raises serious concerns about the benefit-risk assessment, the consistency of the evidence with the intended use, including the medical indication(s) and the post-marketing clinical follow-up plan, NEOEMKI will recommend to the manufacturer to

- limit the intended use of the device to certain groups of patients or certain medical indications,
- and/or requires the manufacturer to limit the validity period of the certificate,
- conduct specific post-marketing clinical follow-up studies,
- modify the user manual or the summary of safety and performance,
- or, where appropriate, impose other restrictions in the conformity assessment report.

The follow-up of the expert committee's opinion is always documented in a report by NEOEMKI.
In its conformity assessment report, NEOEMKI provides exhaustive justification for the cases where it did not follow the advice of the expert committee. Without prejudice to Article 109 of the MDR, the Commission shall make both the scientific opinion of the Expert panels and the written justification provided by the notified body publicly available through the Eudamed database.

### 6.4.2 Procedure in the case of devices incorporating a medicinal substance

Where a device incorporates, as an integral part, a substance which, when used separately, may be a medicinal product within the meaning of Article 1(2) of Directive 2001/83/EC, including a medicinal product derived from human blood or human plasma, and which has an action ancillary to that of the device, the quality, safety and usefulness of the substance shall be verified in accordance with the methods set out in Annex I to Directive 2001/83/EC.

For this reason, before issuing an EU certificate for the evaluation of the technical documentation, NEOEMKI, after having ascertained the usefulness of the substance as part of the device, shall seek an opinion from one of the competent authorities designated by the Member States or the EMA, in accordance with Directive 2001/83/EC, on the quality and safety of the substance, including the risk/benefit balance of incorporating the substance into the device, taking into account the intended purpose of the device. Where the device incorporates a human blood or plasma derivative or a substance which, when used separately, may be considered exclusively as a medicinal product falling within the scope of the Annex to Regulation (EC) No 726/2004, NEOEMKI shall seek the opinion of the EMA.
When giving its opinion, the consulted competent authority for medicinal products will take into account the manufacturing process and the data established by NEOEMKI on the usefulness of the substance for incorporation into a device.
The consulted competent authority for medicinal products shall forward its opinion to NEOEMKI within 210 days of receipt of the necessary documentation.
The opinion of the consulted competent authority for medicinal products, and any possible updates thereof, shall be included by NEOEMKI in the documentation for the device. NEOEMKI shall take due account of the views expressed in

the opinion when making its decision. NEOEMKI may not issue a certificate in the case of an unfavorable opinion and shall refer its final decision to the consulted competent authority for medicinal products.
Before any changes are made to the ancillary material forming part of the device, in particular those related to the manufacturing process, the manufacturer must inform NEOEMKI of the changes. NEOEMKI will assess the opinion of the consulted competent authority for medicinal products to confirm that the quality of the ancillary substance is unchanged, and that the substance remains safe. The consulted competent authority for medicinal products shall consider the data on the utility of incorporating the substance into the device, as determined by NEOEMKI, to ensure that the changes do not adversely affect the previously established risk or benefit of adding the substance to the device. The consulted competent authority for medicinal products shall give its opinion on the changes within 60 days of receipt of the necessary documentation. NEOEMKI may not issue an addendum to the EU certificate for the assessment of the technical documentation in the case of an unfavorable scientific opinion from the consulted competent authority for medicinal products. NEOEMKI shall forward its final decision to the consulted competent authority for medicinal products.
Where the consulted competent authority for medicinal products becomes aware of information that may influence the level of risk or benefit previously established for the incorporation of the substance into a device, it shall provide NEOEMKI with an opinion on whether this information influences the level of risk or benefit previously established for the addition of the substance to the device. NEOEMKI shall take this opinion into account and revise its assessment in the conformity assessment procedure on that basis.

### 6.4.3 Procedure in the case of devices manufactured utilizing, or incorporating, tissues or cells of human or animal origin, or their derivatives, that are non-viable or rendered non-viable

**NEOEMKI has no designation for tissues or cells of human origin or derivatives thereof.**

For devices manufactured using animal tissue rendered non-viable or non-viable products derived from animal tissue referred to in Regulation (EU) No 722/2012, NEOEMKI shall apply the relevant requirements laid down in that Regulation.
Before issuing a certificate for a device, NEOEMKI shall inform the competent authorities of the other Member States and the Commission of the assessment through its own (hereinafter 'coordinating') competent authority (the NCPHP (NNGYK)) by means of a summary assessment report in accordance with Annex II to Regulation (EU) No 722/2012.
The competent authorities of the Member States may comment on the summary assessment report. Two cases are possible:

- In the case where the EDQM TSE compliance certificate of the starting material(s) has been submitted by the customer, they may do so within four weeks of submitting the summary to the coordinating competent authority.
- If the EDQM TSE Certificate of Compliance has not been submitted by the client, it may be submitted within twelve weeks of the submission of the summary.

During the consultation, all questions and comments should be answered - notifying the manufacturer of the Member State's questions and comments. NEOEMKI will then consider all comments and give reasons if one or more comments received have not been taken into account.

NEOEMKI will then make its decision and the final decision of the coordinating competent authority available to the Commission and to the commenting competent authorities.
The manufacturer must notify NEOEMKI of changes and new information on the substance. If NEOEMKI concludes that the TSE risk is increasing or changes are occurring, the consultation should be repeated.

NEOEMKI will repeat the consultation when the certificate is renewed.

### 6.4.4 Procedure in the case of devices that are composed of substances or of combinations of substances that are absorbed by or locally dispersed in the human body

In the case of devices consisting of substances or combinations of substances intended to enter the human body through the body orifices or applied to the skin and which are absorbed or locally distributed in the human body, the quality and safety of the device should be verified, where appropriate and only with regard to requirements not laid down in this Regulation, in accordance with the relevant requirements laid down in Annex I to Directive 2001/83/EC as regards absorption, distribution, metabolism, excretion, local tolerance, toxicity, interaction with other devices, medicinal products or other substances and the possibility of adverse reactions.
In addition, in the case of devices or their metabolites which are systematically absorbed in the human body in order to fulfil their intended purpose, NEOEMKI should seek a scientific opinion from one of the competent authorities designated by the Member States in accordance with Directive 2001/83/EC or from the EMA on the compliance of the device with the relevant requirements set out in Annex I to Directive 2001/83/EC.
The consulted competent authority for medicinal products shall deliver its opinion within 150 days of receipt of the necessary documentation.
The opinion of the consulted competent authority for medicinal products, and any possible updates thereof, will be incorporated by NEOEMKI in the documentation for the device. When taking its decision, NEOEMKI shall take due account of the views expressed in the scientific opinion and shall forward its final decision to the consulted competent authority for medicinal products.

# 7. Reporting obligations of the clients

The customer must notify NEOEMKI after obtaining the certificate:

- if there is a substantial change in its quality system, organizational structure, manufacturing site, technology, product manufactured, etc.; as described in point 7.1.
- about unexpected events related to the products manufactured by it and certified by NEOEMKI as described in point 7.2.
- a certification agreement with a conformity assessment body other than NEOEMKI for the certification of products covered by a certification contract.

## 7.1 Changes

The certification contract concluded between NEOEMKI and the client is valid for the duration of the certification cycle, without any changes to the terms of the contract. In the event of any change that may affect the maintenance of the service ordered by the customer, NEOEMKI shall be obliged to notify the customer without delay, but at least within 30 days, using the form provided for this purpose. The change notification form shall be published by NEOEMKI on its website.
NEOEMKI is not responsible for the consequences of non-reporting by the customer. If NEOEMKI observes changed but not reported circumstances during the initial, surveillance, renewal, extraordinary or unannounced audit or in any other way, it shall be entitled to initiate an amendment of the certification contract and the certification fee.
The customer is obliged to report to NEOEMKI any changes that may have a significant impact on the quality management system and/or product covered by the certification.
NEOEMKI is obliged to carry out a preliminary assessment of all notified changes in order to determine the further action to be taken (e.g.: on-site audit and/or technical documentation assessment, etc.). NEOEMKI is obliged to notify the customer of the results of both the preliminary and, if relevant, the subsequent assessment.

When dealing with changes, the conformity assessment under Regulation (EU) 2017/745 of the European Parliament and of the Council (MDR) shall be carried out in accordance with the first paragraph of point 4.9 of Annex VII to the MDR.
When dealing with changes in conformity assessment procedures, NBOG BPG 2014-3 should always be taken into account.
The obligation to notify changes includes in particular:
**Quality management system** changes regarding: scope (extended/reduced), name, address, headquarters, site, manufacturing site, legal form, organizational structure, management, number of employees, quality manager/designee, person responsible for compliance (PRRC), product scope, technology used, quality management process, subcontractor, supplier, authorized representative (EC REP), etc.
**Concerning the product,** changes regarding: intended purpose of the device, indications, contra-indications, list of the product, name, brand name, specification (technical description), approved device design, approved device type, materials incorporated in or used in the manufacture of the device and their suppliers, manufacturing technology, test method (for both the material used, the semi-finished product and the finished product), packaging, sterilization, shelf life, instruction for use (IFU), label, software, pharmaceutical or raw material of animal origin, the related EU type-examination certificate referred to in point 4 of Annex X, basic UDI-DI, etc.
Specific requirements for conformity assessment procedures:

- Until the change notification is approved by NEOEMKI, the product affected by the change may not be placed on the market.
- For changes to an already approved device, the approval of the certification body must be sought before the change is implemented if the changes may affect the safety or performance of the device or the conditions prescribed for its use.
- If the customer intends to introduce any of the above changes, it must inform NEOEMKI. NEOEMKI shall assess the planned changes and decide whether a new conformity assessment is necessary or whether it is sufficient to grant approval by adding a certificate to the technical documentation assessment. The certification body shall assess the changes, notify the client of its decision and, if it approves the changes, provide the client with an addendum to the EU certificate for the technical dossier evaluation.
- If the assessment of the change by the certification body requires a consultation of authorities, experts or the Commission, NEOEMKI shall carry it out.

## 7.2 Vigilance

The client is obliged to comply with the requirements of Chapter VII, Section 2 of the MDR in relation to the NEOEMKI-certified device.

- to report serious incident under Article 87 and to analyze and manage them under Article 89,
- to notify field safety corrective action under Article 87 and to manage them under Article 89,
- to prepare and report trend reports in accordance with Article 88.

The notifications listed above must be made by the client through the Eudamed system, in compliance with the deadlines set out in the relevant article of the MDR.
The client shall cooperate with the competent authorities and, where appropriate, NEOEMKI in the activities listed above and shall not, without prior notification to the competent authorities, conduct any investigation that involves a change to the relevant instrument or item sample that may affect the analysis of the causes of the incident.

The customer is obliged to inform NEOEMKI within 72 hours of any incident (unexpected event) or accident affecting the product certified by NEOEMKI that occurred during the term of the contract, and the results of the investigation.

The customer is obliged to inform NEOEMKI within 72 hours of any certification procedure initiated by a Member State authority concerning a product during the term of the contract.

Based on the data and information provided in the notification and the results of the manufacturer's investigation, NEOEMKI evaluates the notification and decides whether any action is required and, if so, what level of control the notification requires or whether an extraordinary control needs to be carried out. During its monitoring activities, NEOEMKI checks whether the customer/manufacturer has complied with the above reporting obligations. Failure to comply with reporting obligations may result in a tightening of supervision, an increase in the frequency of surveillance checks, or the suspension or restriction, or even revocation, of the certificate concerned.

If NEOEMKI, as a notified body, establishes after the issue of the certificate of conformity that the certified product no longer meets the requirements or if it has reasonable grounds to suspect that it does not meet the requirements, in particular in the case of a request from a public authority, it shall inform the customer thereof within a period appropriate to the characteristics of the product. If the customer fails to take the necessary measures to bring the product into conformity within the time limit set or if the defect cannot be rectified, NEOEMKI as notified body shall restrict or suspend the validity of the certificate or revoke the certificate. The period of suspension of the certificate shall not exceed 6 months, after 6 months the certificate shall be revoked.

If NEOEMKI, as a notified body, becomes aware after the issue of the certificate of conformity that the device may present a serious public health threat, it is entitled to suspend or revoke the certificate immediately.

## 8. Use of certification, the CE mark and the certification mark

Organizations certified by NEOEMKI can refer to it with the full name printed on their brochures: National Medical Device Conformity Assessment and Certification Ltd. or with the abbreviated name: NEOEMKI.
Along with the first issue of the certificate, NEOEMKI certified customers will receive information about the certification marks and their application rules.
The customer is obliged to comply with the applicable legislation when using the certification mark (CE mark in case of conformity assessment).
NEOEMKI is entitled to exercise appropriate control over the use and display of the certification mark.
Rules for referring to certified status:

- The certificate can be used to prove the certified status within the validity period.
- If the certified status has expired, the organization is no longer entitled to use the certification mark and must cease using it immediately.
- Misleading references to certified status are prohibited.
- The use of certification documents in a misleading way is prohibited.
- In the event of suspension or revocation of certification, all references to certification shall be removed.
- It is prohibited to create the impression that certification also applies to activities or products outside the scope of the application.
- If the scope of certification has been narrowed, all references should be amended accordingly.
- Any reference to the certification of a quality management system and/or product that could damage the reputation of NEOEMKI or the certification system and undermine public confidence is prohibited.
- NEOEMKI will exercise appropriate control and take action if there is an impermissible reference to certified status or misleading use of certification documents, symbols or reports.

NEOEMKI will monitor the use of the certification marks and the references to the certification mark in the customer's/manufacturer's descriptive material during its monitoring activities and reserves the right to call upon the customer to take immediate corrective action in the event of unlawful use of the certification marks, regardless of whether an on-site visit is made.
The privileges that come with certification (both the certificate and the certification mark) expire when the certificate expires or is terminated before its expiry date (e.g. contract termination, suspension or revocation of the certificate). Their use in advertising material is also prohibited thereafter.

Certificates may be photocopied in black and white or in shades of grey, while retaining the original illustrations in an accurate and legible format. Scanned certificates may only be displayed in the form of a color image file by electronic means (e.g. website), copying, writing and in print-protected media.
The certificates issued remain the property of NEOEMKI. After revocation/suspension, the manufacturer must return the certificate to NEOEMKI or destroy it and send written proof of this to NEOEMKI, unless the certificate has expired.
Devices other than custom-made devices and devices intended for clinical investigation which are considered to comply with the requirements of the MDR must bear the CE conformity marking of the manufacturer in accordance with Article 20 of the MDR and Annex V of the MDR.
The CE marking is subject to the general principles laid down in Article 30 of Regulation (EC) No 765/2008.
The CE marking must be affixed visibly, legibly and indelibly to the device or its sterile packaging. Where this is not possible or cannot be ensured owing to the nature of the device, the CE marking must be affixed to the packaging. The CE marking must also appear in the instructions for use and on the commercial packaging of the product.
The CE marking must be affixed before the device is placed on the market. It may be followed by any other pictogram or marking indicating a special risk or use.
For certified devices, the CE marking must always be accompanied by the identification number of NEOEMKI (1011) who is responsible for carrying out the conformity assessment procedure. The identification number must also be indicated on all promotional material mentioning that the device complies with the requirements for the CE marking.
If the devices are subject to other EU legislation that also requires the affixing of the CE marking, the CE marking must indicate that the devices also meet the requirements of that other legislation.

## 7. Document changes

| date | edition | version | modification | justification |
|---|---|---|---|---|
| 2022.07.30 | 00 | 0.2 | Fixing reporting obligations for sending notifications to the electronic system referred to in Article 57 of the MDR. Full review. | OGYÉI - Corrective action related to nonconformity with JAT audit 4.1 (31/2022). |
| 2024.10.09. | 01 | 01 | Initial edition. | NEOEMKI has been designated as the notified body for conducting conformity assessment under MDR (Regulation (EU) 2017/745 on medical devices). |