Centro Nacional de Certificación de Productos Sanitarios (CNCps)

GUIDE FOR CE MARKING FOLLOW UP (MDD/IVDD)

This leaflet is intended to provide information on how to apply for CNCps involvement in the conformity assessment of medical devices to affix the CE marking.

MINISTERIO DE SANIDAD

NCPS CENTRO NACIONAL DE CERTIFICACIÓN DE PRODUCTOS SANITARIOS

Notified Body No. 0318

DEX_01_ Guide for CE marking follow up (MDD/IVDD)_Rev 4

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INFORMATION AND CONDITIONS FOR MAINTENANCE OF CE MARKING (MDD and IVDD)

1. Can the CNCps certify my medical device or in vitro diagnostic medical device?

After the date of application of the new medical device regulations (MDR and IVDR), the actions of the CNCps under the MDD and the IVDD are limited to the follow-up of already issued CE certificates, which includes only follow-up audits and non-significant modifications of the certified devices.

Manufacturers can however apply to the CNCps for the CE marking certification of medical devices under regulation (EU) 2017/745, and in vitro diagnostic medical devices under regulation (EU) 2017/746. For more information, see R_DEX_01 and IVDR_DEX_01 documents on the CNCps website.

2. What is the basis for the proceedings of CNCps?

The actions of the CNCps are governed by the provisions of the MDD and IVDD. For Spanish manufacturers, the provisions of Chapter V of Royal Decree 1591/2009 of 16 October 2009 on medical devices and Chapter VI of Royal Decree 1662/2000 of 29 September 2000 on *in vitro* diagnostic medical devices shall also apply.

These provisions determine that the relationship between the CNCps and the applicant company (manufacturers or other economic operators), shall be established by an agreement signed by both parties.

The CNCps has different forms for the manufacturers that must be filled in and signed by the applicant company, if applicable.

3. What do I need to consider before submitting my application?

The maintenance of the certification is conditional upon the respect of the conditions agreed between the manufacturer and the CNCps. The manufacturer must maintain the approved quality management system (QMS) and keep the technical documentation up to date with the state of the art, demonstrating that the device complies with the essential requirements of Annex I of the applicable directives. It must also implement the post-market surveillance plan, including clinical follow-up or performance evaluation.

The manufacturer must have a system in place to ensure that changes to the device and the approved QMS are adequately controlled.

In addition, from the entry into force of the regulations, manufacturers will have to comply with the requirements of Article 120 of the MDR or Article 110 of the IVDR. These aspects will be audited.

In the application forms, the manufacturer shall clearly identify all subcontractors and/or suppliers distinguishing between critical and non-critical.

The costs of certification services are adjusted and calculated in accordance with public prices (hereinafter PP) and conditions legally established by Order SND/1171/2022, which establishes the public prices applicable to the activities and provision of services to be carried out by the CNCps. The list of services provided by the CNCps and the amount of the public prices to be applied are set out in Annex I.

Critical subcontractors/suppliers are those who supply:

- Finished products.

- Primary packaging and/or labelling services.

- Sterilisation.

- Tests required for batch release.

- Design, manufacturing and control activities that have a significant impact on the conformity of the finished product and for which incoming inspections are not enough. For example, critical components manufacturing

For every application the CNCps issues a quotation that includes the public prices applicable for the requested services and the estimated total cost of such services. This quotation is reflected in the "proforma invoice" that is sent to the applicant through the CNCps platform. The proforma invoice is a preliminar estimation and must be accepted by the applicant in order to continue the process, but it must NOT be paid. Only the definive invoice issued at the end of the process is to be paid by the manufacturer.

During the certification process, it may be necessary to adjust the initial estimation included in the proforma invoice to add or remove some of the planned activities. In this case the estimation will be reviewed and a new profroma invoice will be issued, and sent again to the applicant.

It should be noted that, irrespective of the public prices applicable to the selected procedure, the manufacturer must also pay for the travel expenses, accommodation, and on-site tests arising from the audit to the manufacturer's facilities.

When the procedure is completed, the CNCps will issue a final definitive invoice and send it to the applicant via the CNCps platform. The manufacturer must pay the final invoice within 30 days in order to receive the certificate or final document.

4. How can I get an estimate?

At this stage of the application, only the forms specified for each type of application and in the other points of this document should be attached.

Once the "proforma invoice" has been accepted, the manufacturer must complete the application opened in the CNCps software application with the technical and/or quality documentation.

To obtain a quotation for any CNCps certification service, it is necessary to send an application through the CNCps platform: https://sinaem.aemps.es/CNCps/Login.aspx The user manual is available in the website.

The information contained in those forms will be used for the preliminary assessment of the application. This information will also allow the CNCps to identify which activities or services will be required during the certification process, in order to make an estimate for the proforma invoice. It is very important that the information provided both in the platform and in the forms is as accurate and as detailed as possible.

Forms must be filled, printed as .pdf, and signed with a valid electronic signature. Agreement documents must not be left signature-blocked so that they can be signed by the Head of CNCps.

5. How can I apply for a follow-up audit?

The CNCps carries out periodic follow-up audits and evaluations to verify the maintenance of the approved QMS. The implementation of the PMS plans, the changes made to the device and changes to the approved QMS will be subject to review during these audits. In the context of the follow-up audit, CNCps reviews the technical documentation of the products according to the sampling plan established for the certification cycle.

Periodic follow-up audits shall be carried out every twelve months. The company must apply for a follow-up audit of the CE marking at CNCps at least 3 months before the end of the 12 months after the last audit.

The periodicity of audits may be less than 12 months if necessary to verify the implementation of corrective actions, suspected non-compliance or complaints, occurrence of serious incidents, application for CE marking of new products, changes to the approved quality system, changes in the manufacturing process, due to control or product changes, etc.

audits the CNCps will send an audit plan, informing the auditors, the premises to be visited and proposed dates, in sufficient time for the company to prepare the necessary travel arrangements. The definitive dates for the audit shall be agreed upon receiving the audit plan.

ON0318 is also authorised to carry out unannounced monitoring visits, which may be extended to critical subcontractors and/or suppliers.

For class IIa, IIb, Is and Im devices covered by the MDD, and list B of Annex II devices of the IVDD, whose assessment of the technical documentation is subject to sampling, the audit plan shall state the product(s) whose technical documentation is to be assessed according to the sampling plan. The manufacturer must upload the technical file of the product(s) selected by the CNCps. A PP 4 must be payed for each product to be assessed (see Annex I).

The CE marking follow-up audit application is formalised through the CNCps platform by selecting the "*CE monitoring audit*" option. The request must include:

- Forms needed to prepare the budget for this application:

  - **Mod 93/42/2 *Solicitud de evaluación del sistema de calidad***

    This form shall be signed by the senior management of the applicant company, or the person delegated by them, in which case the document certifying such delegation must be provided.

    In the event that certification arrangements are made by the authorised representative, the application must also be accompanied by the manufacturer's declaration establishing the designation.

- Documentation required to formalise the application:

  - **Documentation of the quality management system:**
    - Quality manual.
    - Organisational chart.
    - List of QMS documents indicating revision and/or revision date.
    - Recording and control of relevant changes, implemented since the last audit, to the quality system and approved devices (design changes and/or new variants).

  - **Technical documentation** of the devices(s) requested by CNCps in the audit plan according to the device sampling plan.

Prior to the audit, the company must attach the completed "Audit Questionnaire" in Word format for each company or subcontractor.

	FORMS	PUBLIC PRICES (see Annex I)
Audit Follow-up	**Mod 93/42/2**	13 o 14 4 (Per technical file) 15 (For each site, if applicable)
Audit and Local Complementary	**Mod 93/42/2**	15 (For each site, if applicable)

Table 1. **Applicable forms and public prices for follow-up and/or repeat audits.**

6. What happens if I modify my device or make changes that affect the manufacturing process or the quality system?

The request for changes requiring approval by CNCps must be made through the CNCps application by selecting the conformity assessment procedure and the corresponding option between "*Modificación del sistema de gestión de calidad" or "Modificación de diseño de producto":*

- Forms needed to prepare the budget for this application:

  - **Mod 93/42/2 Solicitud de evaluación del sistema de gestión de calidad** y/o
  - **Mod 93/42/1 Modificación de condiciones de la certificación**

- Documentation required to formalise the application:

  The technical documentation justifying the modification following the CNCps folder structure. In this case, only the technical documentation is provided in the folders affected by the change, e.g. risk analysis, design and manufacturing, labelling, etc.

The manufacturer is obliged to request approval from the CNCps for any project of modification of the approved QMS: production process, sterilisation, change of facilities or subcontractors and/or critical suppliers, inclusion of new facilities, etc.

From the date of application of the regulations, for products with CE certificates according to the MDD and IVDD only non-significant changes can be made in accordance with MDCG 2020-3 Rev 1 "Guidance on significant changes regarding the transitional provision under Article 120 of the MDR with regard to devices covered by certificates according to MDD or AIMDDD" or "MDCG 2022-6 - Guidance on significant changes regarding the transitional provision under Article 110(3) of the

IVDR".

The notified body shall evaluate the proposed changes, determine the need for additional audits and assess whether the modified QMS continues to satisfy the necessary requirements.

	FORMS	PUBLIC PRICES (see Annex I)
Changes in certification conditions	Mod 93/42/2	6.2 15 (For each site, if applicable)
Non-significant design modifications	Mod 93/42/1	6.2 (per product)

Table 2. Forms and public prices applicable to quality system changes and design modifications.

Approval of a modification requires the payment of the public price 6.2 for each modified device.

If the approval of a modification requires an audit to be carried out, the public price 15 shall also apply, the amount of which depends on the location of the company (see Annex I).

7. How can I apply for batch verification?

This type of application is applicable for batch verification of in vitro diagnostic medical devices of List B of Annex II of the Directive 98/79/EC.

	FORMS	PUBLIC PRICES (see Annex I)
Batch verification	Mod 93/42/8	8 (per batch)

Table 3. Forms and public prices applicable to the request for batch verification

8. How can I apply for administrative changes to my certificate?

Administrative changes are those which do not have a direct impact on the product requirements or on the approved quality system, but which must be communicated to the CNCps, such as changes to:

- The type of legal entity.

- Address of the premises or registered office.
- The authorised representative.
- Senior management positions.

The request for modification of administrative data in a certificate is submitted through the CNCps application by selecting the conformity assessment procedure and the option "Administrative changes to the certificate" and must be accompanied by:

-Application form R_DEX_20 *Solicitud de cambios adminsitrativos* (see Table 6).

-Legal documents proving the requested changes, if applicable, e.g. deeds or notarial documents.

In case of a change of the type of legal entity, or merger of companies, or change of name without modification of the company structure, the applicable "Agreement" forms (see Table 6) must be re-signed.

The only commercial transaction that allows a transfer of the CE marking certificate from one company to another is the merger by adsorption. The purchase or sale of a company does not include the CE marking of its devices.

	FORMS	PUBLIC PRICES (see Annex I)
Administrative changes	Mod 93/42/1	10

Table 4. Forms and public prices applicable to the request for administrative changes to a certificate.

9. What kind of post-certification follow-up information do I have to report to the CNCps?

a. Field security incidents and corrective actions

The manufacturer shall report incidents and field safety corrective actions to the CNCps.

These communications must be made through the CNCps application by selecting "Seguimiento post certificación" and the option " Incidentes/acciones correctivas de seguridad ". All records relating to the same communication must be uploaded to the platform using the same application ID, e.g. initial and final report.

b. PSUR

Manufacturers of Class IIa, IIb and III devices shall prepare a Periodic Safety Update Report (PSUR) required by the new regulations summarising the results and conclusions of the analysis of post-market surveillance data, which shall be updated according to the planned periodicity.

These reports shall be available for review by CNCps during follow-up audits.

10. How can I renounce a product included in my certificate

To renounce one or more devices included in one or more CE certificates, it is necessary to provide the following documentation through the CNCps platform by selecting the evaluation procedure and the option "Renuncia" (see table 9):

A free-format document describing the list of devices to be renounced, including the certificate number as well as the reason for the renounce. This document must be signed by the senior management of the applicant company, or the person delegated by them, in which case the document accrediting this delegation must be provided.

For this procedure, PP 10 shall apply.

	FORMS	PUBLIC PRICES (see Annex I)
Resignation	Free text	10

Table 5. Forms and public prices applied to the processing of the waiver of the CE marking of a product

11. Issuance of express certifications

Any request for the issuance of an explicit certification, other than those provided for by CNCps, requires the payment of a public price "10".

a. Trademarks

In the event that the manufacturer requires the CNCps to explicitly certify that a trademark is covered by an issued certificate, he must request it through the CNCps platform by selecting the certification procedure and the option "Certificación expresa", attaching the following documents:

- Manufacturer's declaration that the content of the accompanying documentation (primary/secondary labelling and IFU) of the new trademark is identical to that included in the accompanying documentation of the CNCps approved product.

- Declaration of conformity, updated, including new trademarks.
- Copy of all documents constituting the labelling/UFI of the device approved by the Notified Body.
- Copy of all documents constituting the labelling/IFU of the rebranded device.

No communication to CNCps is required for approval of new trademarks. During follow-up audits it shall be confirmed that the trademarks are included in the declaration of conformity and in the technical documentation.

The devices marketed under the different brands must be identical to the certified device (composition, purpose, indication, etc.) and their labelling and IFUs must be a true copy of those approved by the CNCps.

b. Other express certifications

In the event that the manufacturer requires the CNCps to explicitly certify any particular aspect not included in the reports or certificates issued, this must be requested through the CNCps platform by selecting the certification procedure and the option "Certificación expresa" and including a written proposal for the text to be included in the certificate. CNCps will assess the possibility of issuing the certification and the suitability of the proposed text.

	FORMS	PUBLIC PRICES (see Annex I)
Express certification	**Free text**	10
Issuing written trademarks	**Free text**	10

Table 6. **Forms and public prices applied to the issuance of an express certification.**

12. How can I apply for a letter of confirmation under Regulation (EU) 2023/607?

CNCps has enabled in the CNCps application the possibility to request a confirmation letter for manufacturers to demonstrate to third parties that a formal application for conformity assessment of a product (or a product intended to replace it) under Regulation (EU) 2017/745 (MDR) has been submitted to CNCps and that they have a written agreement signed by both parties, in order to benefit from the extension of the transitional period deadlines under Regulation (EU) 2023/607.

The extension shall apply to manufacturers that:

- comply with the conditions set out in points (a), (b), (c) and (d) of Article 120(3c) of Regulation (EU) 2023/607.
- who have submitted to the CNCps the application for CE marking in accordance with the Regulation (EU) 2017/745 by 26 May 2024.
- and have a formal agreement signed by both parties by 26 September 2024.

Devices for which the conditions are fulfilled may be placed on the market or put into service until the following dates:

- 31 December 2027, for all devices in class III and for implantable devices in class IIb other than suture material, staples, dental filling materials, orthodontic appliances, dental crowns, screws, wedges, plates, wires, pins, clips and connecting devices;
- on 31 December 2028 for devices in Class IIb other than those referred to in point (a) of this paragraph, for devices in Class IIa, and for devices in Class I placed on the market in sterile condition or having a measuring function.

Manufacturers complying with the above can apply for the confirmation through the CNCps platform by selecting the following options: "Seguimiento CE de productos sanitarios (MDD y IVDD)"→ "Seguimiento post-certificación" →"Extensión de Certificado CE (Reg. 2023/607 – Reg. 2024/1860)".

	FORMS
Letter of Confirmation Regulation 2023/607	DEX_03 "REQUEST FOR CONFIRMATION LETTER REGULATION (EU) 2023/607". Agreement signed by both parties (R_DEX_02 and/or R_DEX_22).

Table 7. Forms that must be used to apply for a confirmation letter (Regulation (EU)2023/607)

The application for the confirmation letter does not require the payment of any public price.

13. How can I apply for a letter of confirmation under Regulation (EU) 2024/1860?

Manufacturers of in vitro diagnostic medical devices may also request a letter of confirmation to demonstrate to third parties that a formal application for conformity assessment of a device (or a device intended to replace a device) under Regulation (EU) 2017/746 (IVDR) has been submitted to CNCps and that they have a written agreement signed by both parties, in order to benefit from the extension of the transitional period deadlines under Regulation (EU) 2024/1860.

The extension shall apply to manufacturers that:

- Fulfil the conditions referred to in points (a), (b), (c) and (d) of Article 110(3c) of Regulation (EU) 2024/1860,
- Have lodged an application for CE marking with the Notified Body in accordance with the IVDR by:
    - 26 May 2025, for products for which a certificate according to Directive 98/79/CE has been previously issued and is valid.
    - For products without a certificate according to Directive 98/79/CE, the application must be submitted before:
        - 26 May 2025, in the case of class D products.
        - 26 May 2026, for class C Devices
        - 26 May 2027 for Class B devices and sterile Class A Devices
- Have a formal agreement signed by both parties before:
    - 26 September 2025, in the case of devices for which a certificate according to Directive 98/79/EC has been previously issued and is valid.
    - In the case of products without a certificate according to Directive 98/79/CE, the agreement must be signed before:
        - 26 September 2025, in the case of class D products
        - 26 September 2026, in the case of class C products
        - 26 September 2027, for Class B and sterile Class A products

Under the Regulation, products for which the conditions are met may be placed on the market or put into service until the following dates:

- 31 December 2027, in the case of products for which a certificate according to Directive 98/79/EC has been previously issued and is valid.
- In the case of products without a certificate according to Directive 98/79/EC, the deadline for the extension of the transitional period shall end on the following dates:
    - 31 December 2027, in the case of class D Devices
    - 31 December 2028, in the case of class C Devices
    - 31 December 2029 for class B devices and sterile class A Devices

IVDD DEVICES	1st DEADLINE: APPLY FOR IVDR CERTIFICATION TO A NB	2nd DEADLINE: SIGN AGREEMENT FOR IVDR CERTIFICATION WITH AN NB	EXTENSION PERIOD
Devices with an IVDD CE certificate Class D devices which did not require a CE certificate under IVDD	26/05/2025	26/09/2025	31/12/2027
Class C devices which did not require a CE certificate under IVDD	26/05/2026	26/09/2026	31/12/2028
Class B devices which did not require a CE certificate under IVDD Class A Sterile devices which did not require a CE certificate under IVDD	26/05/2027	26/09/2027	31/12/2029

Manufacturers complying with the above can apply for the confirmation letter through the CNCps platform by selecting the following options: "Seguimiento CE de productos sanitarios (MDD y IVDD)"→ "Seguimiento post-certificación" →"Extensión de Certificado CE (Reg. 2023/607 – Reg. 2024/1860)".

	FORMS
Letter of Confirmation Regulation 2024/1860	IVDR_DEX_03 "REQUEST FOR CONFIRMATION LETTER REGULATION (EU) 2024/1860". Agreement signed by both parties (IVDR_DEX_02)

Table 8. Forms that must be used to apply for a confirmation letter (Regulation (EU)2024/1860)

Annex I. Public price code and type of activity or service (Order SND/117172022)

PUBLIC PRICE CODE	TYPE OF ACTIVITY OR SERVICE		UNIT PRICE EXCLUDING VAT (EUROS).
1	Preliminary assessment		430
2	Assessment of the complete technical documentation of a medical device		4.012
3	Assessment of specific aspects of the technical documentation of a medical device		2.293
4	Sampled technical documentation review		2.866
5	Inclusion of a medical device belonging to a category or generic already certified		860
6	Assessment of modification of design or certification conditions		
6.1	Major modifications		2.006
6.2	Minor modifications		573
7	Periodic Safety Updated Report (PSUR) assessment; Summary of Safety and Performance Assessment (SSP) assessment		860
8	Device verification or batch verification		358
9	Issuance of specific reports (Type Examination Report, Medicinal Substance or Absorbed Substance Report, Expert Report, Screening Procedure, etc.)		1.720
10	Issuance of a certification document		215
11	Audit of complete quality management system (Initial or Stage 2)		
11.1	In Spain	1 - 50 employees	5.732
11.2		> 50 employees	8.024
11.3	Outside Spain	1 - 50 employees	6.878
11.4		> 50 employees	9.171
12	Audit in accordance with production quality assurance (Initial or Stage 2)		
12.1	In Spain	1 - 50 employees	4.012
12.2		> 50 employees	6.305
12.3	Outside Spain	1 - 50 employees	5.159
12.4		> 50 employees	7.451
13	Periodic follow-up audit of complete quality management system.		
13.1	In Spain	1 - 50 employees	3.439
13.2		> 50 employees	5.732
13.3	Outside Spain	1 - 50 employees	4.585
13.4		> 50 employees	6.878
14	Periodic follow-up audit of production quality assurance.		
14.1	In Spain	1 - 50 employees	2.866
14.2		> 50 employees	4.012
14.3	Outside Spain	1 - 50 employees	4.012
14.4		> 50 employees	6.305
15	Stage 1 audits, audits to additional premises or "repetion audits		
15.1	In Spain		2.293
15.2	Outside Spain		3.439
16	Annual certification maintenance fee		358

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