Centro Nacional de Certificación de Productos Sanitarios

Information and Conditions: CE marking IVDR

2025

MINISTERIO DE SANIDAD

CNCPS CENTRO NACIONAL DE CERTIFICACIÓN DE PRODUCTOS SANITARIOS

Organismo Notificado 0318

IVDR_DEX_01 Information and Conditions

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Index

1. What is CNCps?

The CNCps is the Centro Nacional de Certificación de Productos Sanitarios ("National Certification Center for Medical Devices"), a sub-directorate general attached to the Spanish Agency for Medicines and Medical Devices (AEMPS), which is responsible for acting as a Notified Body and for the certification of quality system standards specific to the medical devices sector.

2. What is the legal basis for the CNCps' procedures?

The p of the CNCps are governed by the provisions of Regulation 2017/746, of 5 April, on "in vitro" diagnostic medical devices, hereinafter IVDR. For Spanish manufacturers, the provisions of Chapter VI of Royal Decree 1662/2000 of 29 September on in vitro diagnostic medical devices also apply.

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

The CNCps has different forms for the manufacturers (summarised in Table 1) that must be filled in and signed by the applicant company, if applicable.

IVDR application forms
IVDR_DEX_02_Acuerdo CNCps fabricante IVDR
IVDR_DEX_04_Productos IVD
R_DEX_05_FOR01_Instalaciones
R_DEX_05_Solicitud de evaluación del sistema de gestión de calidad
IVDR_DEX_03 Solicitud de carta de confirmación Reglamento 2024/1860
R_DEX_03_FOR02_Declaración de estado de expediente
R_DEX_06_Solicitud de recertificación CE
IVDR_DEX_07_Solicitud de modificación de condiciones de la certificación
R_DEX_12_Solicitud comunicación PSUR y SSCP/SSP
IVDR_DEX_15_Solicitud de verificación de lotes de producto
R_DEX_20_Solicitud cambios administrativos
R_DEX_16_Acuerdo CNCps Artículo 16

Table1 . IVDR application forms.

When the first application is made to the CNCps, the corresponding agreement shall be signed by the senior management of the applicant company. This agreement shall be renewed when the application for recertification is made and in the event of any changes to the conditions signed in the agreement during the certification period.

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

The current scope of designation of the CNCps to act as Notified Body 0318 for in vitro diagnostic medical devices can be found on the European Commission website at the following link: EUROPA – European Commission – Growth – Regulatory policy - SMCS

Only applications for which the CNCps has previously confirmed that it has sufficient and appropriate resources for certification will be accepted.

4. What do I need to consider before submitting the CE marking application?

4.1. Confirm qualification and classification

When submitting its application for CE marking, the manufacturer shall inform the classification proposal for its devices. Classification shall be carried out in accordance with the criteria and rules set out in Annex VIII of the IVDR and the MDCG classification guides in force (MDCG 2020-16, MDCG 2024-11).

In case of doubt, it is advisable to request a prior opinion on qualification and/or classification from the Competent Authority of the Member State where the manufacturer (or its Authorized Representative) it's located. In case of dispute about the classification between the manufacturer and the Notified Body, the decision will be reffered to said Competent Authority.

In addition, the manufacturer shall identify the Regulation (UE) 2017/2185 codes applicable to the device, both the IVR code as well as the horizontal codes reflecting the specific characteristics of the device (IVS/IVP/IVD) and the horizontal codes describing the applicable technologies or manufacturing process (IVT). The CNCps can only certify devices whose codes (IVR, IVS, IVP, IVD, IVT) are included in the scope of its designation (see point 3).

The manufacturer shall also identify in the application the generic group applicable to the devices. The generic group shall be described as the 3rd level of the EMDN nomenclature (i.e. Combination of one letter plus four digits) in Combination with the IVP code applicable to the device.

The CNCps does not foresee any special procedure for the transfer of CE marking certificates from another notified body. These applications will be handled as a standard initial application.

4.2. Demonstrate compliance with GSPR

Before applying for CE marking, the manufacturer must have demonstrated and documented the device's conformity with all the applicable general safety and performance requirements (GSPR). The manufacturer shall also demostrate that is able to manufacture devices in conformity with these requirements. The general requirements apply to all devices, regardless of their classification.

Demonstration of compliance with the GSPR shall include a performance evaluation covering scientific validity, analytical and clinical performance based on scientifically valid, reliable and robust clinical evidence.

The manufacturer may use harmonised standards, common specifications and MDCG guidelines to justify and document the conformity of the device with these requirements. This documents are used as reference for both competent authorities and notified bodies. The harmonised standards that have been published so far can be found on the European Commission's website.

The IVDR_DEX_04 table of GSPR is available at the CNCps's website.

The MDCG 2022-2 "Guidance on general principles of clinical evidence for In Vitro Diagnostic medical devices (IVDs)" and the applicable common specifications (Implementing Regulation (EU) 2022/1107 common specifications for certain Class D in vitro diagnostic medical devices), will be the reference for the evaluation of clinical data by the CNCps and can be a useful tool for manufacturers. The UNE-EN 13612:2002 "Performance evaluation of in vitro diagnostic medical devices" standard will be used as a reference document for performance evaluation studies. In the case of software, the reference for performance evaluation will be the MDCG 2020-1 Guidance on Clinical Evaluation (MDR) / Performance Evaluation (IVDR) of Medical Device Software.

4.3. Choose an evaluation procedure

The manufacturer shall choose the applicable conformity assessment procedure taking into account the classification of the device. The manufacturer must also consider which procedure is the best fit for the quality management system implemented by the company.

The evaluation of the technical documentation shall be carried out following a sampling plan according to the MDCG 2019-13. The evaluation of the technical documentation prior to certification shall be performed as follows:

- Class D, self-testing products and products for point-of-patient care (PPT): no sampling

is performed, the technical documentation of each of the products shall be evaluated.

- Class C: technical documentation of at least one device per generic group (third level of the EMDN nomenclature, in combination with the IVP code) shall be assessed.
- Class B: the technical documentation of at least one product per category (IVR codes) shall be assessed.
- Class A sterile: the technical documentation (aspects related to obtaining and maintaining sterilisation) of at least one product per sterilisation method shall be assessed.

Once the products have been certified, the sampling plan will continue to be applied during the annual monitoring, until the certification cycle is completed.

CNCps can only certify devices according to the evaluation procedures included in the scope of designation summarised in Table 2 below.

Procedure for evaluation Ranking	Quality management system (Annex IX, Chapter I and III)	Assessment of technical documentation (Annex IX, Chapter II)	Production Quality Assurance (Annex XI Part A)	EU Declaration of Conformity (Article 17 and Annex IV)
CLASS D	X	X		X
CLASS C	X	(Review of technical documentation of at least one device per generic group)		X
CLASS B	X	(Review of technical documentation of at least one device per generic group per category)		X
SELF-TESTING DEVICES (NOTE: class D, C and B)	X	X (Each and every techical documentation will be reviewed, regardless of class)		X
DIAGNOSTIC TESTS AT THE POINT OF PATIENT CARE (NPT) (NOTE: class D, C and B)	X	X (Each and every techical documentation will be reviewed, regardless of class)		X
CLASS A STERILE	X	(Review of technical documentation of at least one device per type of sterilisation)	X	X
TYPE OF CERTIFICATE ISSUED BY CNCps	EU Quality Management System Certificate	EU Technical Documentation Assessment Certificate NOTE; only for Class D, self-testing and point-of-care (POC)	EU Quality Assurance Certificate	

Table2 . Conformity assessment procedures, classes of devices and types of certificates obtained

4.4. Identify all critical sub-contractors and suppliers

In the application, the manufacturer shall clearly identify all subcontractors and/or suppliers distinguishing between critical and non-critical. They shall be identified in the form R_DEX_05_FOR01 "Instalaciones".

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, manufacturing of critical components.

4.5. Certification costs

The costs of certification services are calculated in accordance with the legally established public prices (hereinafter PP). The list of services provided by the CNCps and the public prices to be applied are listed in Annex II.

The applicable PPs for device certification are described in Annex I. In addition, the applicant must take into account the PPs applicable to each additional procedure listed in Table 3.

Additional procedures	Public price
Performance Evaluation Consultation Procedure, Article 48 Section 6 (Class D devices)	9
Informe de evaluación de la documentación técnica (productos clase D, autodiagnóstico y NPT)	
Expert evaluation report	

Table3 . Public prices applicable to additional procedures.

The required PPs for all other applications are described in detail in the relevant sections of this document.

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. Such will be the case if, for example, the consulted expert has had to dedícate more time than initially anticipated or if the expert has had to issue more than one report for the same device.

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 this final nvoice within 30 days in order to receive the final document requested (CE marking certificate, explicit certification, etc).

The CNCps reserves the right to issue, withdraw or suspend a certificate until the applicant has paid the full amount included in the final invoice.

5. If I already have a product on the market under Directive 98/79/EC, can I benefit from the extension periods under Regulation (EU) 2024/1860?

Manufacturers of legacy in vitro diagnostic medical devices can benefit from the extension periods

To request a confirmation letter, an application must be placed in the CNCps platform by selecting 'Extension of CE Certificate (Reg. 2023/607 - Reg. 2024/1860)'. For more information, please consult the document DEX_01 'Information and conditions CE Marking (MDD_IVDD)' available on the CNCps website.

set out in Regulation (EU) 2024/1860 provided that they have submitted a formal application to a notified body for conformity assessment of a device (or a device intended to replace it) under Regulation (EU) 2017/746 (IVDR), and have a written agreement signed by both parties.

In the event that the manufacturer, at the time of placing the initial IVDR certification application, does not yet have the technical documentation complete or fully aligned with the IVDR, the manufacturer must provide, together with the applicable application forms, the form R_DEX_03_FOR02 "Declaracion estado expediente" indicating the aspects of the technical file incomplete or not aligned with the requirements of the IVDR that would result in the application for certification NOT being accepted. In this case, a 'conditional' admission for processing will be made, on condition that the manufacturer provides the complete technical documentation within the deadline. The application will remain in 'conditional admission for processing' status and will remain at a standstill, without any action on the part of the CNCps, until the applicant communicates that it is ready to submit the documentation.

6. How can I get an estimate?

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.

If the manufacturer wants to apply for CE marking for several devices at the same time, they must make separate applications following the system below:

- Class D devices, self-testing, or diagnostic tests at the point of patient care: one application per device.
- Class C devices: one application for each group of devices belonging to the same generic group (3rd level of EMDN + IVP code).
- Class B devices: one application for each group of devices belonging to the same category (IVR code).
- Class A sterile devices: one application for each group of devices sterilized by the same sterilization method (if they are all sterilized by the same method, it will be a single application).

If several applications are made for the same evaluation procedure, the first one will be made using the "Initial application" option and the rest will be made using the "New product" option.

In the initial stage of the application, only the required forms according to Annex I and this document should be attached.

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.

The following are the forms necessary to draw up the initial application estimate for CE marking certification (see Annex I):

- IVDR_DEX_04 *Acuerdo CNCps-fabricante IVDR*.
  This agreement must be signed by senior management
- R_DEX_05 *Solicitud de evaluación del sistema de gestión 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.
- R_DEX_05_FOR01_*Instalaciones*
  Excel form in which the manufacturer shall provide information on the facilities where device-related activities are carried out e.g. manufacturing, packaging or sterilisation, whether it is the organisation's own facilities or subcontractor/supplier's.
- IVDR_DEX_04_*Productos*
  Excel form in which the manufacturer shall provide information on the products for which initial certification according to the IVDR is requested.

In the case of legacy manufacturers who, at the time of making the initial application for IVDR certification, do not yet have complete or fully aligned technical documentation with the IVDR, and wish to benefit from the time extension provided for in Regulation (EU) 2024/1860, the following document must also be provided:

- IVDR_DEX_03_FOR02_*Declaracion estado expediente*
  Form in which the manufacturer must inform the aspects of the technical documentation that are still incomplete or not fully aligned with the IVDR.

In cases where the manufacturer wants to apply for certification of several devices under different conformity assessment procedures, there must be as many initial applications as different assessment procedures selected.

7. How does CNCps process my application and how long will it take for my device to be certified?

7.1. Preliminary assessment

The CNCps performs a preliminary assessment based on the information included in the application forms. This assessment is used to confirm several things. First, that the device is an in vitro diagnostic medical device and that it is well classified. Then, the capacity of CNCps to carry out the certification process (scope of designation, resources) is also confirmed. With all that information, the CNCps makes an estimation for the certification process, taking into account all the activities to be carried out for certification, e.g. audits of the manufacturing company's facilities and subcontractors.

The manufacturer then receives via the CNCps application the "proforma invoice" which must be accepted by the applicant.

This preliminary assessment subject to payment of PP 1. If the application is finally accepted for processing, this amount will be deducted from the final invoice.

The CNCps can't accept applications for product conformity assessment for the same assessment procedure that have been already submitted to another Notified Body.

7.2. Application review and acceptance for processing

Once the "proforma invoice" has been accepted, the manufacturer must complete the application initiated by providing the device's technical documentation and the QMS documentation. In this phase, CNCps verifies that the manufacturer has all the necessary documentation to demonstrate compliance with the GSPR, taking into account the device's intended purpose.

Documentation required to formalise the application:

- Deeds of incorporation of the company
- Documentation of the quality management system:
  - Quality manual
  - Organisation chart
  - List of QMS documents indicating revision and/or revision date

  - Procedure for post-market surveillance (PMS) and, where appropriate, post-market performance follow-up (PMPF)
  - Procedure for vigilance
  - Procedures for conducting risk analysis and performance evaluation
  - Procedure for the allocation of UDI

- Technical documentation supporting the conformity of the devices following the CNCps folder structure described in the IVDR_DEX_18 "Guidance for IVDR Technical Documentation" guideline:
  - For Class D devices, self-testing and Near Patient Testing (NPT) devices, the complete technical file for every device.
  - For Class C, B, and A sterile devices, the complete technical file shall be submitted if the initial application only includes a single device. If the initial application includes more than one Class C, B or A sterile device, only the technical documentation included in folder 1 "Index" and folder 2 "Description and specifications" of each device shall be submitted. The CNCps will then select one or more of those devices to be reviewed according to the sampling plan, and the manufacturer will be asked to upload the full technical documention for this device.

The technical documentation provided must contain the provisions of Annexes II and III of the IVDR, and must also comply with the stipulations of the CNCps in the public document "Guía para la documentación técnica" (IVDR_DEX_18). CNCps will carry out a preliminary assessment of the technical documentation provided, with special attention to the aspects related to the performance evaluation. If deficiencies are detected, through the CNCps application, by means of the action 'Deficiencias evaluación preliminar", the

CNCps reserves the right to request updated technical files at any time if deemed necessary for conformity assessment.

necessary clarifications will be requested in order to be able to make a decision on whether or not to admit the application for processing, and may require new missing or incomplete documentation to be provided.

The language for the submission of applications shall be, at least, Spanish. However, the submission of technical, scientific or specialised documentation in English may be accepted, the Notified Body reserving the right to request a translation into Spanish if the complexity of the subject matter so requires it.

If the documentation is considered adequate, the application will be accepted for processing"("admisión a trámite"). This "admisión" entails the establishment of the deadline for resolution, which takes into account the procedure, the number of products included in the procedure and their classification, the technological complexity of the products and industrial processes, the involvement or not of experts, the need or not to carry out audits and/or tests/verifications, the number and geographical location of the facilities. The applicant company must accept the deadlines and conditions through the application in order to continue with the procedure and start the conformity assessment process.

Under no circunstace may applications be accepted for devices whose performance evaluation does not meet the requirements laid down in Article 56 of the IVDR. Applications for devices for which the manufacturer has not performed the applicable verifications and validations according to the characteristics of the device won't be accepted either.

The deadline allocated to evaluate the technical documentation could be extended in the case of class D products, which have to be submitted to verification by a common European reference laboratory and which in case of Devices whithout common specifications that are first certification of its type will be subject to the Performance Evaluation Consultation Procedure (PECP).

The completion time of the process is conditioned by the adequacy of the documentation submitted, the speed of the company's response to possible deficiencies, the need for pre-audit testing, the results of the audit and the speed with which the company can resolve any non-conformities that may be detected.

In the event that the documentation submitted does not comply with the established requirements, the CNCps requests that the deficiencies detected be rectified within 10 days. This period may be

extended up to three months at the request of the interested party, provided that this request is duly justified. If this period elapses without the deficiencies having been rectified, the CNCps will refuse to process the application ("no admisión a trámite") and this fact will be communicated to EUDAMED as 'Application refusal (by NB)'.

If it is the manufacturer who decides to request the withdrawal of his application, he must indicate this in a free text document, after which CNCps will issue a corresponding acknowledgement of receipt of the withdrawal and will communicate this fact to EUDAMED as 'Withdrawn application (by MF)'.

It is important that applicants only formalise applications for projects that are completed and conform with IVDR requirements. The CNCps will have to report to EUDAMED any application not admitted for processing (Annex VII point 4.3) or withdrawn by the manufacturer.

7.3. Evaluation of technical documentation

The conformity assessment procedure starts with the evaluation of the technical documentation. During the process, CNCps may request further additional documentation or tests. If the intervention of an external expert is deemed necessary during the assessment, the manufacturer will be informed and the initial quotation will be revised. The CNCps uses available harmonized standards, common technical specifications, other technical standards or European guidelines as a reference for evaluating the conformity of the device. In the assessment of the performance evaluation, the CNCps will use the MDCG guidelines available at the time of the evaluation.

The technical documentation review process by the CNCps includes a maximum of three rounds of communication of deficiencies to correct any non-conformities that may arise regarding the technical file. Therefore it is of utmost importance that device projects are completely finalized before sending the application to the CNCps.

In the case of Class D devices, in addition:

- For class D 'in vitro' diagnostic medical devices for which an EU reference laboratory (EURL) has been designated, CNCps shall request a EURL to verify, by laboratory testing, the performance declared by the manufacturer and the conformity of the device with the common specifications or other applicable solution allowing to ensure an equivalent level

of safety and performance. In the absence of an EURL, the testing laboratory shall be requested to verify, by laboratory testing, the performance declared by the manufacturer and to analyse samples of devices or batches of devices. PP 9 shall apply.

- For these products, the manufacturer must commit to submit to the CNCps the control and test reports of each manufactured batch, by filling in and signing the corresponding Agreement (IVDR_DEX_09). After certification, this documentation of each batch must be sent for verification together with the form IVDR_DEX_15. PP 8 (see Annex II) shall apply.
- In addition, the manufacturer shall submit samples of batches of products manufactured in accordance with the conditions and provisions previously agreed between the CNCps and the manufacturer for the purpose of the relevant tests to be carried out by the EURL involved in the initial certification. The fees established by the EURL shall apply.
- In the case of class D in vitro diagnostic medical devices for which no common specifications exist and which are the first certification of their type, the CNCps will consult the European Commission's expert panel on the performance report submitted by the manufacturer (PECP). PP 9 (see Annex II) shall apply.

7.4. Conducting an audit

When the CNCps has assessed the conformity of the techical documentation, it will audit the QMS system of the manufacturer through a visit to its facilities, and if deemed necessary, the subcontractor's and/or critical supplier's. Its QMS system in place must ensure that activities that may have an impact on the quality of the medical device are properly controlled.

For audits of additional premises, subcontractors and/or critical suppliers, PP 15 shall apply.

The CNCps will decide whether an on site audit of the critical subcontractors and/or suppliers is necessary, taking into account its impact on the conformity of the device and the degree of control exercised by the manufacturer.

The CNCps will sent an audit plan through the application in the CNCps platform, informing the audit team, premises to be visited and dates for the audit. This plan will be sent with sufficient time for the manufacturer to prepare the necessary travel arrangements.

The audit of the CNCps will be carried out following the R_POT_7.3_FOR03 "Cuestionario de auditoría" document, which is based on UNE-EN ISO 13485:2018/A11:2022[1] , the harmonised

[1] UNE-EN ISO 13485 is equivalent to EN ISO 13485 and ISO 13485.

standard for quality assurance systems for medical devices. This questionnaire will be available in the CNCps It must be completed and sent back in Word format. This questionnaire may also be required for other sites or critical subcontractors/suppliers-

The audit team will communicate the results of the audit to the manufacturer in the audit report. In case of non-conformities or observations, the CNCps will establish a deadline for the submission of the corrective action plan (CAPA).

The company must send the duly completed form R_DEX_08 "Corrective Action Plan", together with the documentation that proves that the deficiencies have been rectified, via the CNCps platform within the established deadline. In some cases, evaluation of corrective actions for non-conformities may require a new audit to confirm proper implementation of corrective actions.

Once the corrective action plan has been reviewed, the audit team will issue its final report, with the conclusions, which will be sent to the company via the CNCps platform.

Failing to meet the deadlines set for the submission of the corrective action plan or submitting an incomplete corrective action plan may be cause for certificate suspensión or withdrawal.

Having an ISO 13485 certificate shall not exempt the manufacturer, subcontractor and/or critical supplier from undergoing the QMS audit by the CNCps

7.5. Issuing the CE marking certificate

The CE marking certificate is issued when the conformity of the device has been confirmed through the review of its technical documentation, testing of the device (if applicable) and the QMS audit to the manufacturer's facilities.

If the conformity assessment process establishes that the device or the quality management system is not conform with the requirements of the IVDR, the CE marking will not be granted.

The period of validity of the certificate will depend on the information gathered by the CNCps during the evaluation process and may be subject to specific conditions or limitations. In no case shall the period of validity exceed five years.

The CNCps will not issue a CE marking certificate until the final definitive incovice has been paid.

8. I have my certificate, what should I do now?

The manufacturer is obliged to maintain the approved QMS and its capability to ensure compliance with the applicable product requirements. The manufacturer must also implement the post-market surveillance (PMS) plan, including post-market performance follow-up (PMPF).

In addition, the manufacturer must have a system in place to ensure that changes to the product and to the approved QMS are adequately controlled.

There's an anual fee (PP 16) required for the yearly maintenance of every CE certificate.

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.

Likewise, as part of the documentation required for a periodic follow-up audit application, the complete technical documentation of the device or devices requested in the audit plan shall be provided. The device for technical documentation review shall be chosen based on the sampling plan established for the certification cycle, and the information gathered by the CNCps since the initial certification. For every technical documentation to be reviewed, the PP 4 is to be paid.

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.

As in the initial audit, for the periodical follow-up 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.

Pursuant to the certification agreement and in compliance with IVDR legal requirements, the CNCps is authorised to carry out unannounced audits to the manufacturer's facilities, including subcontractors and/or critical suppliers.

The CE marking follow-up audit application is formalised through the CNCps platform by selecting the "auditoría de seguimiento CE" option. The application must include:

- Forms needed to issue the proforma invoice (see Table 4):
  - R_DEX_05 *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.
  - R_DEX_05_FOR01 *Instalaciones*
    Excel form in which the manufacturer shall inform the locations where activities related to the device are carried out e.g. manufacturing, packaging or sterilisation. This includes the manufacturer's own facilities and subcontractors/suppliers.
- Documentation required to formalise the application:
  - Documentation of the quality management system:
    - Quality manual
    - Organisation chart
    - List of QMS documents indicating revision and/or revision date
    - Records and control of relevant changes, implemented since the last audit, to the QMS and to the device (design changes or addition of new variants).
  - Technical documentation of the device(s) requested by the CNCps in the audit plan for review according to the device sampling plan.

	FORMS	PUBLIC PRICES
Audit Follow-up	R_DEX_05 R_DEX_05_FOR01	13 or 14, as applicable (See Annex II) 4 (Per product sample evaluation) 15 (For each site, if applicable)
Audit of Repetition and audit of Complementary Premises	R_DEX_05 R_DEX_05_FOR01	15 (For each site, if applicable)

Table4 . Applicable forms and public prices for follow-up and/or repeat audits.

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

The application for changes requiring approval by the CNCps must be made through the CNCps platform by selecting the conformity assessment procedure and the corresponding option: "Modificación sistema gestión de calidad", "Modificación de diseño de producto" or "Ampliación de gamas de producto".

Forms needed to issue the proforma invoice:

- IVDR_DEX_07 Modification of certification conditions
- IVDR_DEX_04 *Productos IVD* or R_DEX_05_FOR01 *Instalaciones* depending on the scope of the requested change (See Table 5).

Documentation required to formalise the application:

- The technical documentation justifying the modification following the folder structure described in the IVDR_DEX_18 Technical documentation guide available at the CNCps website. In this case, only the technical documentation in the folders affected by the change has to be provided, e.g. risk analysis, design and manufacture, labelling, etc.

9.1. Approved quality system changes

The manufacturer, regardless of the classification of the device, is obliged to seek approval from the CNCps for any project of significant modification of the approved QMS, e.g. change of manufacturing technology, production process, sterilisation, change of facilities or subcontractors and/or critical suppliers, etc.

The Notified Body shall evaluate the proposed changes, determine the need for additional audits and verify whether the modified QMS continues to satisfy the previously approved requirements.

The forms and public fees required to apply for approval of changes to the QMS system are described in Table 5.

9.2. Changes to the approved product

The manufacturer must document all modifications made to each certified device (design modification and/or addition of new variants) and verify that the changes introduced do not compromise the conformity of the device(s) with the GSPR.

For devices with an EU technical documentation certificate (Class D devices, devices for self-testing and point-of-care devices), the manufacturer shall apply for an approval from the notified body of:

- Any change in the design of the certified device which may affect conformity with the GSPR or with the conditions of use of the product: specifications, raw materials or components, packaging materials, labels, instructions for use, etc.
- Addition of new models, dimensional variants, new presentations, etc.

For class C, B and A sterile devices:

The manufacturer shall keep a design history record with the modifications made to the device. This record shall be provided to the CNCps in the follow-up audit application.

	FORMS	PUBLIC PRICES
Quality system changes	IVDR_DEX_07 R_DEX_05_FOR01 (if applicable) IVDR_DEX_04 (if applicable)	6.1 15 (For each site, if applicable)
Design modifications (Class D, self-diagnostic and NPT only)	IVDR_DEX_07 R_DEX_05_FOR01 (if applicable) IVDR_DEX_04 (if applicable)	Minor 6.2 (per device) Major 6.1 (per device) 15 (For each site, if applicable)
Expansion of the product range (class D, self-diagnostic and NPT only)	IVDR_DEX_07	6.2 (Per device) 15 (For each site, if applicable)

Table5. Forms and public prices applicable to QMS changes, device design modifications and new variants

For the modification approval, a Public Price must be paid for each product (see Table 5). If the modification approval requires an on-site audit, the public price 15 shall also apply.

10. How can I apply to include a new product in my CE certificate?

Once the manufacturer has a CE marking certificate issued by CNCps, the application for new products must be formalised through the CNCps platform by selecting the conformity assessment procedure and the option "Nuevo producto", creating as many independent applications as necessary (see point 6 of this document).

10.1. Class D, and Class C or B self-diagnostic devices or near patient testing (NPT) devices

Forms needed to issue the proforma invoice for this application:

- IVDR_DEX_07 *Solicitud de modificación de las condiciones de certificación*
  This form shall be signed by the senior management of the applicant company, or the person delegated by them, in which case the document accrediting such delegation must be provided.
- IVDR_DEX_04_*Productos*
  Excel form in which the manufacturer shall provide information on the devices to be certified
- R_DEX_05_FOR01_*Instalaciones*
  Excel form in which the manufacturer shall inform the locations where activities related to the device are carried out e.g. manufacturing, packaging or sterilisation. This includes the manufacturer's own facilities and subcontractors/suppliers.

Documentation required to formalise the application:

- Complete technical documentation supporting the conformity of the device following the CNCps folder structure described in the "Guide for IVDR technical documentation". To ensure traceability of the documentation in the CNCps platform it is important that the device names recorded in the application and in the IVDR_DEX_04 "Productos" form are one and the same, and identical to the device name on the label and in the technical documentation.

10.2. Class C, B and A sterile products

Forms needed to prepare the budget for this application:

- IVDR_DEX_07 *Solicitud de modificación de las condiciones de certificación*
  This form shall be signed by the senior management of the applicant company, or the person delegated by them, in which case the document accrediting such delegation must be provided.
- IVDR_DEX_04_*Productos*
  Excel form in which the manufacturer shall provide information on the devices to be certified
- R_DEX_05_FOR01_*Instalaciones*
  Excel form in which the manufacturer shall inform the locations where activities related to the device are carried out e.g. manufacturing, packaging or sterilisation. This includes the manufacturer's own facilities and subcontractors/suppliers.

Documentation required to formalise the application:

Technical documentation: Only the technical documentation included in folder 1 "Index" and folder 2 "Description and specifications" of each device must be submitted. To ensure traceability

of the documentation in the CNCps platform it is important that the device names recorded in the application and in the IVDR_DEX_04 "Productos" form are one and the same, and identical to the device name on the label and in the technical documentation.

The CNCps shall review the information provided and, if the new device belongs to a generic group (class C) or category (class B or A sterile) already certified, it will include the new device in the sampling plan. PP 5 shall apply.

If the new device does not belong to a category or generic group already included in the certificate or if it represents a new worse case considering the generic group or category already evaluated, the manufaturer will be asked to send the full technical documentation. PP2 shall apply in this case.

If the inclusion of a new device in the certificate requires a previous QMS on-site audit, PP 13 and/or 15 respectively (see Annex II) shall also apply.

11. What to consider when applying for recertification?

The company shall review and, if necessary, update the technical documentation of the certified devices to ensure conformity with the legislation and the state of the art. This review shall consider all product experience gathered in the post-production phase.

To apply for the issuance of a new certificate (recertification), the manufacturer must choose the procedure "Auditoría de Recertificación CE" (see Table 7) in the CNCps platform. The following documentation shall be attached:

- Agreement signed by senior management (IVDR_DEX_02).
- R_DEX_06 *Solicitud de recertificación*
  This form shall be signed by the senior management of the applicant company, or the person delegated by them, in which case a document certifying such delegation must be provided.
- IVDR_DEX_04_*Productos*
  Excel form in which the manufacturer shall provide information on the devices to be certified
- R_DEX_05_FOR01_*Instalaciones*

  Excel form in which the manufacturer shall inform the locations where activities related to the device are carried out e.g. manufacturing, packaging or sterilisation. This includes the manufacturer's own facilities and subcontractors/suppliers.

Documentation required to formalise the application:

- Deeds of incorporation of the company.

- QMS documents:
  - Quality manual.
  - Organisation chart
  - List of QMS documents indicating revision and/or revision date
- Technical documentation for Class D devices, self-testing devices and point-of-care (PTC) diagnostic tests to be re-certified. A summary report must be included including:
  - All changes to the initially approved device, including changes not yet notified.
  - Experience gained in post-market surveillance (PMS), risk management, demonstration of GSPR compliance.
  - Experience gained from performance evaluation reviews, including the results of performance studies and post-market performance follow-up (PMPF).
  - Changes to device components or scientific or regulatory context.
  - Changes to harmonised standards, common specifications or equivalent documents, whether applicable or new.
  - Changes in medical, scientific and technical knowledge, such as: new treatments, changes in testing methods, new scientific discoveries about materials and components, including discoveries concerning their biocompatibility; experience gained from studies on comparable devices; data from registries and databases; experience gained from performance studies with comparable devices.

	FORMS	PUBLIC PRICES
Audit recertification	IVDR_DEX_02 R_DEX_06 R_DEX_05_FOR01 IVDR_DEX_04	13 or 14, as applicable (see Annex II) 15 (if applicable) 10 (per certificate to be issued) 2, 3 or 4 (as applicable for each device to be reviewed) 9 (for each Class D product, self-diagnostic or diagnostic test in lieu of patient care NPT)

Table6 . Forms and public prices applicable to the recertification audit.

Prior to carrying out the audit, the company must attach the completed "Audit Questionnaire" in Word format, which is available in the CNCps application.

The company must apply for recertification at least 6 months before the expiry date of the certificate (9 months for class D devices).

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

12.1. Incidents and field safety corrective actions (FSCAs)

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.

12.2. PSUR and SSP

Manufacturers of class C and D devices shall prepare a periodic safety update report (PSUR) summarising the results and conclusions of the analysis of post-market surveillance data which is updated according to the planned periodicity.

In the case of class C devices, the manufacturer must keep it at the disposal of the CNCps and submit it when required, e.g. in the context of follow-up audits.

For class D devices, the manufacturer shall submit PSUR updates on a regular basis via the CNCps platform selecting "Seguimiento post certificación" and then the option "PSUR".

In addition, for Class D devices the manufacturer shall also submit any modifications to the summary of safety and performance (SSP) through the CNCps platform, selecting "Seguimiento post certificación" and the option "SSP".

The application must be accompanied by form R_DEX_012 " Solicitud comunicación PSUR Y SSP" (see Table 8).

	Form	PUBLIC PRICES
PSUR	R_DEX_12	7
SSP	R_DEX_12	7

Table7 . Forms and public prices applicable to PSUR and SSP.

13. How can I renounce to my device or apply for the suspension of my certificate?

If during the certification cycle the company wishes to renounce one or more devices included in one or more CE certificates, or temporarily suspend an issued CE certificate, it must do so through the CNCps application by selecting the evaluation procedure and the option "Renuncia" or "Suspensión", as appropriate (See table 9).

The application must include a free-format document describing the list of devices to be renounced or the certificate to be suspended, including the certificate number as well as the reason for the renounce or suspension. 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.

	FORM	PUBLIC PRICES
Renounce or suspension	Free text	10

Table 9. Forms and public prices applied to the processing of the waiver of the CE marking for a product

14. I am a distributor/importer carrying out relabelling and/or repackaging activities. How do I apply for certification of this activity?

The distributor or importer that carries out relabelling and/or repackaging activities of "in vitro" diagnostic medical devices certified in accordance with the IVDR can request a certificate on its activity from this Notified Body. To do so, the distributor/importer must be registed in the CNCps platform and select the activity "Relabelling, reconditioning and repackaging (art. 16 IVDR)", choosing the selected procedure from the drop-down menu.

14.1. Initial Application

Forms needed to issue a proforma invoice for this application (see Table 11):

- Agreement signed by top management (R_DEX_16 CNCps Agreement for Article 16)
- R_DEX_05 *Solicitud de evaluación del sistema de gestión de calidad*
  This form shall be signed by the senior management of the applicant company, or the person delegated by them, in which case a document certifying such delegation must be provided.
- R_DEX_05_FOR01_*Instalaciones*

  Excel form in which the manufacturer shall inform the locations where activities related to the device are carried out e.g. manufacturing, packaging or sterilisation. This includes the manufacturer's own facilities and subcontractors/suppliers.

Documentation required to formalise the application:

- Deeds of incorporation of the company.
- Documentation of the quality management system:
  - Quality manual
  - Organisation chart
  - List of QMS documents indicating revision and/or revision date

14.2. Modification of certification conditions, follow-up audits and recertification

Certificates issued in accordance with Article 16 are also subject to regular monitoring and control by the Notified Body.

The modification of the initial certification conditions, including the extension of the activity to devices other than those already certified, must be communicated through the CNCps platform, providing the necessary supporting documentation for the approval of the new certification conditions.

Periodic follow-up and recertification audits are carried out in accordance with the audit programme established by the Notified Body. However, the company must send the application for the certification follow-up audit in the CNCps application at least 3 months before the completion of the 12 months after the last audit was carried out. The same applies for re-certification applications where the Agreement signed by the top management must be provided again (IVDR_DEX_16 CNCps Agreement Article 16).

Forms needed to prepare the budget for this application (see Table 11):

- R_DEX_05 *Solicitud de evaluación del sistema de gestión de calidad*
  This form shall be signed by the senior management of the applicant company, or the person delegated by them, in which case a document certifying such delegation must be provided.
- R_DEX_05_FOR01_*Instalaciones*
  Excel form in which the manufacturer shall inform the locations where activities related to the device are carried out e.g. manufacturing, packaging or sterilisation. This includes the manufacturer's own facilities and subcontractors/suppliers.

	FORM	PUBLIC PRICES

Certification of activity of relabelling and/or repackaging (Art. 16)	R_DEX_16 R_DEX_05 R_DEX_05_FOR01	11 or 12 as applicable (see Annex II) 10 15 (For each site, if applicable)
Modification of the conditions for the certification of the activity of relabelling and/or repackaging (Art. 16)	R_DEX_05 R_DEX_05_FOR01	10 6.1 15 (For each site, if applicable)
Follow-up audit	R_DEX_05 R_DEX_05_FOR01	13 or 14 as applicable (see Annex II) 15 (For each site, if applicable)
Recertification audit	R_DEX_16 R_DEX_05 R_DEX_05_FOR01	13 or 14 as applicable (see Annex II) 10 15 (For each site, if applicable)

Table 11. Forms and public prices applicable to the certification of the re-labelling and/or repackaging activity.

15. How can I request 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
Administrative Changes	R_DEX_20 R_DEX_02 (if applicable) IVDR_DEX_02 (if applicable) R_DEX_16 (if applicable)	10

Table8 . Forms and public fees applicable to the request for administrative changes to a certificate.

16. Issuance of explicit certifications.

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

16.1. 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.

16.2. Other explicit 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.

	FORM	PUBLIC PRICES
Express certification	Free text	10
Issuing written trademarks	Free text	10

Table 13. Forms and public prices applied to the issuance of an express certification.

Annex I. Summary of the applicable procedures according to type of device. Forms and public prices applicable to initial applications and new in vitro diagnostic medical devices are included.

	Annex XI		Annex IX (Chap I, III)		Annex IX (Chapters I, II, III)	
	Forms	**Public Prices**	**Forms**	**Public Prices**	**Forms**	**Public Prices**
Class A sterile	**INITIAL APPLICATION** IVDR_DEX_02 IVDR_DEX_04 R_DEX_05 R_DEX_05_ FOR01	1 See Annex II) 3 (per each sterilisation cycle) 15 (Per supplementary premi	**INITIAL APPLICATION** IVDR_DEX_02 IVDR_DEX_04 R_DEX_05 R_DEX_05_FOR01	11 See Annex II) 3 (per each sterilisation cycle) 15 (Per supplementary premise		
	REQUEST FOR NEW DEVICES IVDR_DEX_04 R_DEX_05_FOR01 IVDR_DEX_07	3 (if different Category) or 5 (if same Category) 13 (if applicable) 15 (Per supplementary premises)	**REQUEST FOR NEW DEVICES** IVDR_DEX_04 R_DEX_05_FOR01 IVDR_DEX_07	3 (if different Category) or 5 (if same Category) 13 (if applicable) 15 (Per supplementary premise		
Class B			**INITIAL APPLICATION** IVDR_DEX_02 IVDR_DEX_04 R_DEX_05 R_DEX_05_ FOR01	11 (See Annex II) 2 (for each category) 15 (Per supplementary premise		
			REQUEST FOR NEW DEVICES IVDR_DEX_04 R_DEX_05_FOR01 IVDR_DEX_07	2 (if different Category) or 5 (if same Category) 13 (if applicable) 15 (Per supplementary premise		
C-Class			**INITIAL APPLICATION** IVDR_DEX_02 IVDR_DEX_04 R_DEX_05 R_DEX_05_ FOR01	11 (See Annex II) 2 (per generic) 15 (Per supplementary premise		
			REQUEST FOR NEW DEVICES IVDR_DEX_04 R_DEX_05_FOR01 IVDR_DEX_07	2 (if different Generic) or 5 (if same Generic) 13 (if applicable) 15 (Per supplementary premise		
Class D					**INITIAL APPLICATION** IVDR_DEX_02 IVDR_DEX_04 R_DEX_05 R_DEX_05_ FOR01	11 (See Annex II) 2 (per device) 9 (per device) 15 (Per supplementary premises)
					REQUEST FOR NEW DEVICES IVDR_DEX_04 R_DEX_05_FOR01 IVDRR_DEX_07	2 (per device) 9 (per device) 13 (if applicable) 15 (Per supplementary premises)
					BATCH VERIFICATION REQUEST IVDR_DEX_15	8 (per batch)
Self-diagnostic or Near Patient Testing (NPT) devices					**INITIAL APPLICATION** IVDR_DEX_02 IVDR_DEX_04 R_DEX_05 R_DEX_05_ FOR01	11 (See Annex II) 2 (per device) 9 (per device) 15 (Per supplementary premises)
					REQUEST FOR NEW DEVICES IVDR_DEX_04 R_DEX_05_FOR01 IVDRR_DEX_07	11 (See Annex II) 2 (per device) 9 (per device) 13 (if applicable) 15 (Per supplementary premises)

Annex II. Public 30esig codes and type of activity or service (SND Order No. 1171/2022)

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 design modifications 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 (Technical Documentation Assessment Report, Expert Report, PECP 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

Failure to comply with the commitments acquired with the Notified Body, as well as failure to comply with the deadlines set for the submission of the analysis of the non-conformities detected during the conformity assessment process, or failure to submit the analysis within the deadline without the non-conformities having been completely rectified, may be cause for suspension or withdrawal of the certificates awarded.

CENTRO NACIONAL DE CERTIFICACIÓN DE PRODUCTOS SANITARIOS

MINISTERIO DE SANIDAD

CNCPS CENTRO NACIONAL DE CERTIFICACIÓN DE PRODUCTOS SANITARIOS

MINISTERIO DE SANIDAD

agencia española de medicamentos y productos sanitarios