IVDR

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IVDR : FAQs (continued)

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Glossary of Terms

IVDR : FAQs (continued)

Regulatory

Q: What is IVDR?

IVDR stands for *In-vitro* Diagnostic Regulation and is a European regulation from the European Parliament and of the Council of Europe of 5 April 2017 on *in vitro* diagnostic medical devices.

IVDR is a European Regulation and therefore applies to all EU countries. IVDR also impacts other regions where CE mark devices are commercialized. It is required to check national legislations for the ones outside-of EU countries to perform complete impact assessment.

UK has a transition period where it will accept IVDR, until own UK legislation is fully launched and applicable.

Switzerland has translated IVDR into its own national law (IVDO).

Q: Which countries does IVDR apply to?

In Europe, IVDR is applicable in 27 European Union (EU) member countries:

Austria	Belgium	Bulgaria	Croatia	Cyprus	Czech Republic
Denmark	Estonia	Finland	France	Germany	Greece
Hungary	Ireland	Italy	Latvia	Lithuania	Luxembourg
Malta	Netherlands	Poland	Portugal	Romania	Slovakia
Slovenia	Spain	Sweden			

It applies to **Non-EU countries** part of the European Economic area (EEA):

- Norway
- Iceland
- Liechtenstein

IVDR applies to Northern Ireland and Turkey which are not part of the EU and EEA countries.

Countries with product registrations that rely on the CE certificate

IVDR impacts other regions where CE mark devices are commercialized. An assessment of requirements by the national legislations for the ones outside-of EU countries will be performed.

Q: How will we transition customers from IVDD to IVDR?

A cut-over date will be established for each test and customers will be informed in advance of this date with a customer letter. At the cut-over date, Cepheid will shift from producing IVDD products and to production of IVDR products. This transition will impact all regions using CE-marked products.

The IVDR LEx team will provide a launch timeline for each country/region.

IVDR : FAQs (continued)

Q: What does NPT mean? Why have some products been renamed with an NPT part number? What are the differences between NPT tests and non-NPT tests?

Products with a Near-Patient Testing (NPT) claim are specifically intended for use in near-patient testing environments such as emergency units, patient homes, or workplaces. These products must have clinical data that demonstrates their performance when used by non-laboratory healthcare workers in these settings, and they require additional validation studies with intended users.

Products with NPT claim requires paper IFU to be included within every kit.

Q: What defines a product without an NPT claim under IVDR?

Non-NPT products are intended for use in controlled laboratory environments by trained professionals. These products do not require the same usability studies as NPT products but still need to meet IVDR requirements for clinical evidence, safety, and performance.

Q: Which tests will have an NPT claim under IVDR?

Eight products are targeted to have an NPT claim:

- Xpert® **Xpress** CoV-2/Flu/RSV ***plus***
- Xpert® **Xpress** CoV-2 ***plus***
- Xpert® **Xpress** Flu/RSV
- Xpert® MTB/RIF Ultra (NPT)
- Xpert® HIV-1 Qual XC
- Xpert® **Xpress** GBS
- Xpert® CT/NG (NPT)
- Xpert® HCV VL Fingerstick

Q: Are systems and collection devices already IVDR compliant?

Systems (instruments) and Collection Devices are Class A products under IVDR, the lowest risk class according to the new IVDR classification system. Those products do not require a Notified Body oversight. Class A products are the only class that is self-declared by the manufacturers under IVDR. It means no certificates are issued by Notified Bodies for those products. Manufacturers sign a (Declaration of Conformity) DoC to declare conformity to current legislation. Marketing material for those products should not show the notified body number 2797.

There is no transition period for Class A products. It means all Class A products were required to have a signed DoC before the IVDR Date of Application (DoA) in May 2022. All instruments and collection devices, for those intended to be commercialized under IVDR, have IVDR compliant documentation (Technical Documentation) and have a signed DoC before that date.

IVDR : FAQs (continued)

Product and Technical

Q: Which tests are being transitioned to IVDR?

Franchise	Product Name (class)	IVDR Part number (Bold - new Part no.)	NPT	New ADF*	Changes to test claims, performance, storage, specimen or design
HAI	Xpert Norovirus (B)	GXNOV-CE-10	No	No	None anticipated
HAI	Xpert MRSA NxG (B)	GXMRSA-NXG-CE-10	No	No	None anticipated
HAI	Xpert *C.difficile* BT (B)	GXCDIFFBT-CE-10	No	No	None anticipated
HAI	Xpert *vanA/vanB* (B)	GXVANA/B-CE-10	No	No	None anticipated
HAI	Xpert SA Nasal Complete (C)	GXSACOMP-CE-10	No	No	None anticipated
HAI	Xpert MRSA/SA SSTI (C)	GXMRSA/SA-SSTI-CE	No	No	None anticipated
HAI	Xpert MRSA/SA Blood Culture (C)	GXMRSA/SABC-CE-10	No	No	None anticipated
HAI	Xpert Carba-R (B)	GXCARBARP-CE-10	No	No	None anticipated
Oncology & Genetics	Xpert Bladder Cancer Detection (C)	GXBLAD-CD-CE-10	No	No	None anticipated
Oncology & Genetics	Xpert Bladder Cancer Monitor (C)	GXBLAD-CM-CE-10	No	No	None anticipated
Oncology & Genetics	Xpert Breast Cancer STRAT4 (C)	GXBCSTRAT4-CE-10	No	No	None anticipated
Oncology & Genetics	Xpert BCR-ABL Ultra (C)	GXBCRABL-10	No	No	None anticipated
Oncology & Genetics	Xpert FII & FV (C)	GXFIIFV-10	No	No	None anticipated
Respiratory	Xpert **Xpress** CoV-2/Flu/RSV ***plus*** (D)	**XPRS4PLEX-CE-10**	Yes	Yes	Yes
Respiratory	Xpert **Xpress** CoV-2 ***plus*** (D)	**XPRS-COV2-CE-10**	Yes	Yes	Yes
Respiratory	Xpert **Xpress** Strep A (B)	XPRSTREPA-CE-10	No	No	None anticipated
Respiratory	Xpert **Xpress** Flu/RSV (B)	**XPRSFLU/RSV-NP-10**	Yes	Yes	Yes
SH	Xpert CT/NG (NPT) (C)	**GXCT/NG-NP-10**	Yes	Yes	Yes
SH	Xpert TV (C)	GXTV-CE-10	No	No	None anticipated
SH	Xpert **Xpress** GBS (C)	XPRSGBS-CE-10	Yes	No	None anticipated
SH	Xpert HPV v2 (C)	**GXHPV2-CE-10**	No	Yes	None anticipated
TB	Xpert MTB/XDR (C)	GXMTB/XDR-10	No	No	None anticipated
TB	Xpert MTB/RIF Ultra (C)	GXMTB/RIF-ULTRA-10	No	No	None anticipated
TB	Xpert MTB/RIF Ultra (NPT) (C)	**GXMTB/RIF-U-NP-10**	Yes	Yes	Yes
Virology	Xpert HBV Viral Load (D)	GXHBV-VL-CE-10	No	No	None anticipated
Virology	Xpert HCV Viral Load (D)	GXHCV-VL-CE-10	No	No	None anticipated
Virology	Xpert HCV VL Fingerstick (D)	**GXHCV-FS-NP-10**	Yes	No	None anticipated
Virology	Xpert HIV-1 Viral Load XC (D)	GXHIV-VL-XC-CE-10	No	No	Yes
Virology	Xpert HIV-1 Qual XC (D)	**GXHIV-QA-XC-CE-10**	Yes	No	None anticipated

*Assay Definition File

None anticipated - no changes are expected in the claims, performance, storage, specimen and design based on the IVDR submission which are pending final signed DOC

IVDR : FAQs (continued)

Q: What are the timelines for IVDR launches and will these vary by regions? When will customers start receiving the IVDR version of the test?

IVDR conversion will start in Q2 2025 and end in late 2026, depending on the country's registrations (except for HPV v2, which will be launched earlier).

It will be a global cut-over date. Cepheid may have to build stock to supply to countries with long registration timelines.

A launch timeline will be provided once we get closer to launch.

Q: How will the IVDR launch plan be communicated internally?

Internal communications will consist of series of educational sessions starting in December 2024 and supported by an internal IVDR transition FAQ.

Q: How will customers be informed about the launch and the transition timelines?

The CEP IVDR webpage is now available under the support section of the country home page (here) and provides helpful information on Cepheid's IVDR transition. Customers will receive a general announcement letter providing high-level information, and detailed information about the products 4 months before launch. Cepheid internal teams will be trained to provide information and answer questions.

Q: How will customers be able to differentiate between IVDD and IVDR kits?

A coloured sticker attached to the front of IVDR kits will distinguish kits from IVDD versions.

Q: Are there any changes to the existing tests with IVDR versions?

The IFU for all products will have a change.

A few products are expected to have changes to performance or design (refer to table above). Changes to tests will be confirmed once the approved IVDR DoC has been received. These changes will be communicated internally and prior to their launch.

Customer letters will be provided prior to launch to communicate any changes to the IVDD versions.

Q: Will any of the IVDR products be CD-less?

The Xpert **Xpress** CoV-2 plus and Xpert **Xpress** CoV-2/Flu/RSV ***plus*** will be CD-less. The ADF/IFU will be available on the product webpage.

There is no change in CD strategy with IVDR conversion for other IVDD tests.

Q: Will there be Assay Definition File (ADF) updates for IVDR versions be updated and different from the IVDD version? If yes, how will they be different and can the IVDD version and IVDR version co exists on the same GeneXpert system?

Changes to ADF will be confirmed once we have the approved Declaration of Conformity (DoC) documents. These changes and impact to customers will be communicated internally prior to the launch and details provided in customer letters.

The Xpert **Xpress** CoV-2 ***plus***, Xpert **Xpress** CoV-2/Flu/RSV, Xpert HPV v2, Xpert MTB/RIF Ultra (NPT), and Xpert CT/NG (NPT) will have new ADFs.

IVDR : FAQs (continued)

Q: Can customers use their IVDD stock while they start receiving IVDR products?

Customers can use their IVDD products until expiry date. We encourage customers to use up IVDD stock before switching to IVDR.

Q: Will there be any change in the price for the IVDR versions?

No. There will be no change in prices or contracts. Customer tenders/contracts should be updated for the seven products with a new cat number.

Q: What is the impact on the customer site for products where there are no changes?

All products: Customers will have to upload the new IFU.

The new version of the product will begin shipping with a flyer that includes instructions on how to locate the updated IFU, and the stickers below will appear on all new kits that have the updated Assay Import Instructions:

For the products with an ADF update:

The new version of the product will begin shipping with a flyer that includes instructions on how to locate the updated IFU and ADF, and the stickers below will appear on all new kits that have the updated ADF and Assay Import Instructions:

There is no need to do any conversion, customers will receive a launch announcement and start receiving the product with the new labelling.

Q: What is the impact on the customer site for products where there are changes to the performance, storage or specimen collection?

Customers will be notified of the changes in the customer letter with side-by-side product comparisons. This can be used to evaluate the impact on their site.

Q: What is the plan to transition customer orders to new IVDR products versions?

The aim is to inform customers 3 months prior to the transition to allow time for transition, inform procurement and update contract accordingly.

Q: Do customers have to run a verification study?

According to each country regulation on laboratory accreditation, test re-verifications could be required, especially if the customer is using a non-NPT test in POC settings or the performance of the product changes.

For tests where no changes have been made apart from product registration under IVDR, verification should not be necessary. Ultimately, it's up to the labs to assess whether a verification study is needed.

IVDR : FAQs (continued)

Marketing Information

Q: How will the marketing collateral be changed for IVDR?

Each device shall be accompanied by the information needed to identify the device and its manufacturer, and by any safety and performance information relevant to the user or any other person, as appropriate. Such information may appear on the device itself, on the packaging or in the instructions for use, and shall, if the manufacturer has a website, be made available and kept up to date on the website.

All customer-facing documents, including distributor-facing materials, need correct IVDR-labelling by adding the CE2797 symbol for products that require notified body oversight. Additionally, changes will be included in case of claim updates.

Q: Which customer care collaterals will be updated?

Essential collaterals such as Internal Technical Training presentations, assay-specific knowledge base articles, and Laboratory Information System (LIS) guidance will be updated/created based on IVDR specific requirements.

Q: Will new training material be available for IVDR products?

The essential collaterals will be updated by time of launch. All customer facing training materials will be created for the IVDR products.

Q: When will our CEP internal teams be trained?

Information will continuously be shared during large meeting and training is planned to be rolled out from the end of 2024.

Q: Will Cepheid provide training on IVDR for customers?

Customer facing training material will be updated and IVDR overview slides included.

A general announcement letter will be sent to customers. We also plan to do digital communications to inform customers about our plans and post latest updates on the IVDR webpage.

Q: How can the batches in SAP inventory be identified as either IVDD or IVDR?

There is an “IVD regulatory control” flag in the batch classification in SAP, which can either designate “IVDD Regulations” or “IVDR Regulations”.

Glossary of Terms

IVDR: *In Vitro* Diagnostic Regulation, the European regulation for diagnostic devices

NPT: Near-Patient Testing, tests conducted close to patient locations such as clinics or mobile units

IVDD: *In Vitro* Diagnostic Directive, the previous regulation replaced by IVDR

DoC: Declaration of Conformity, a manufacturer’s declaration that a product meets regulatory standards