Cepheid
A better way.

Confidence. It comes from knowing that you have the right partner for IVDR compliance.

Cepheid is on track to finalize IVDR certification

and implement all requirements for **more than 30 tests** and the **GeneXpert® systems**.

100%

IVDR Compliance for the GeneXpert Systems and Collection Devices

>30

Xpert Tests on Track to Be IVDR Certified

Cepheid shares the values of transparency and health protection for patients and users championed by the IVDR and is committed to supporting all our customers and distributors during this transition phase.

Our IVDR Roadmap for Xpert Tests

IVDR CLASS D
BLOOD-BORNE VIROLOGY
HBV VL, HCV VL, HIV-1 VL XC, HIV-1 QUAL XC, HCV VL FINGERSTICK
MAY* 2025

IVDR CLASS D
RESPIRATORY
COV2/FLU/RSV, COV2
MAY* 2025

IVDR CLASS C
ONCOLOGY AND GENETICS
BLADDER CANCER DETECTION, STRAT4, BCR-ABL ULTRA, BLADDER CANCER MONITOR, NPM1, p190, FII & FV
MAY* 2026

IVDR CLASS C
WOMEN'S AND SEXUAL HEALTH
CT/NG, HPV, GBS, TV
MAY* 2026

IVDR CLASS C
HAI
SA NASAL COMPLETE, MRSA BC
MAY* 2026

IVDR CLASS C
INFECTIOUS DISEASES
MTB/RIF ULTRA, MTB XDR
MAY* 2026

IVDR CLASS B
RESPIRATORY
FLU/RSV
MAY* 2027

IVDR CLASS B
HAI
CARBA R-P, MRSA NXG, C. DIFF BT, MRSA/SA SSTI, NOROVIRUS, VANA/VANB
MAY* 2027

IVDR conversion product roadmap subject to change.

Supporting You at Every Step

In each phase of the IVDR compliance journey, we're right by your side, confidently headed in the right direction.

* At latest. By 26 May 2022 all new IVDs placed on the market and Class A non-sterile devices had to comply with the IVDR. All IVDD CE certified devices must comply with the IVDR by 26 May 2025 or upon certificate expiry. Depending on the risk class, the transition period for IVDD self-declared devices is 26 May 2025 for Class D devices and extends to 26 May 2026 for Class C devices and to 26 May 2027 for Class B and A sterile devices. On 27 May 2027, all devices must comply with IVDR.

CE-IVD. *In Vitro* Diagnostic Medical Device. May not be available in all countries.

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