EU DECLARATION OF CONFORMITY

	Cepheid 904 Caribbean Drive Sunnyvale, CA 94089 USA Single Registration Number (SRN): US-MF-000010979
EC REP	Cepheid Europe SAS Vira Solelh 81470 Maurens-Scopont France Single Registration Number (SRN): FR-AR-000001368
Device Trade Name	GeneXpert® Dx Systems GeneXpert® System with Touchscreen
Basic UDI-DI	081164701-GX-X5
REF	GeneXpert II (GX-II) GeneXpert IV (GX-IV) GeneXpert XVI (GX-XVI)
Device Intended Purpose	**GeneXpert® Dx Systems** **Intended Use** The GeneXpert Dx system is an in vitro diagnostic device intended for use with Cepheid Xpert® test kits. The GeneXpert Dx system automates and integrates sample preparation, nucleic acid amplification, and detection of the target sequence in simple or complex samples using real-time Polymerase Chain Reaction (PCR). The system is designed for hands-off processing of patient samples (specimens) and provides both summarized and detailed test results data in tabular and graphic formats. **Intended User / Environment** The GeneXpert Dx system is intended to be used by laboratory professionals or specifically-trained healthcare users in a laboratory and near patient test setting as specified in the Cepheid Xpert test instructions for use. **GeneXpert® System with Touchscreen** **Intended Use** The GeneXpert System with Touchscreen automates and integrates sample preparation, nucleic acid amplification, and detection of the target sequence in simple or complex samples using real-time Polymerase Chain Reaction (PCR). The system is suited for in vitro diagnostic applications that require hands-off processing of patient samples (specimens) and provides summarized and detailed test results data in tabular format. The GeneXpert systems with touchscreen are designed for the use of Cepheid Xpert® test applications.

	Intended User / Environment The GeneXpert System with Touchscreen is intended to be used by laboratory professionals or specifically-trained healthcare users in a laboratory and near patient test setting as specified in the Cepheid Xpert test instructions for use.

We, as the manufacturer of the device(s) take sole responsibility for and hereby declare that the above mentioned device(s) meet(s) the provisions of the following Regulation(s)/Directives:

Regulation EU 2017/746 on *in vitro* Diagnostic Medical Devices	
Risk Class	A ☒ B☐ C☐ D☐
Classification Rule	Annex VIII, Rule: 5(b) Instruments intended by the manufacturer specifically to be used for *in vitro* diagnostic procedures
Conformity Assessment Route	☐ Annex IX(I) Quality Management System ☐ Annex IX(II) Technical Documentation ☐ Annex X Type Examination ☐ Annex XI Production Quality Assurance ☒ Annex II & III (class A only)
Common Specification	Not applicable
Notified Body	Not applicable
Notified Body Number	Not applicable
Certificate(s)	Not applicable

Additional Information
As the GeneXpert Dx systems are configurable devices, each of the following configurations are covered by this EU Declaration of Conformity:

GXII-1-L, GXII-1-D, GXII-2-L, GXII-2-D
GXII-1-D-10C, GXII-1-L-10C, GXII-2-L-10C, GXII-2-D-10C
GX-TSK, GXII-1-TSK, GXII-2-TSK,

GXIV-1-L, GXIV-1-D, GXIV-2-L, GXIV-2-D, GXIV-3-L, GXIV-3-D, GXIV-4-L, GXIV-4-D, GXIV-1-HE-L, GXIV-1-HE-D, GXIV-2-HE-L, GXIV-2-HE-D, GXIV-3-HE-L, GXIV-3-HE-D, GXIV-4-HE-L, GXIV-4-HE-D
GXIV-1-L-10C, GXIV-1-D-10C, GXIV-2-L-10C, GXIV-2-D-10C, GXIV-3-L-10C, GXIV-3-D-10C, GXIV-4-L-10C, GXIV-4-D-10C
GXIV-1-TSK, GXIV-2-TSK, GXIV-3-TSK, GXIV-4-TSK

GXXVI-4-L, GXXVI-4-D, GXXVI-8-L, GXXVI-8-D, GXXVI-12-L, GXXVI-12-D, GXXVI-16-L, GXXVI-16-D

GXXVI-4-L-10C, GXXVI-4-D-10C, GXXVI-8-L-10C, GXXVI-8-D-10C,
GXXVI-12-L-10C, GXXVI-12-D-10C, GXXVI-16-L-10C, GXXVI-16-D-10C
GXXVI-4-TSK, GXXVI-8-TSK, GXXVI-12-TSK, GXXVI-16-TSK

Signed on behalf of Cepheid, by:

Suzette Chance
Suzette Chance (Dec 12, 2023 12:29 PST)

Dec 12, 2023
Date of Issue

Suzette Chance
Vice President, Regulatory Affairs

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