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	Xpert® Urine Specimen Collection Kit
Basic UDI-DI	081164701-URINE/A-LG
REF	URINE/A-50
Device Intended Purpose	**Intended Use** The Xpert® Urine Specimen Collection Kit is designed to preserve and transport *Chlamydia trachomatis, Neisseria gonorrhoeae*, and *Trichomonas vaginalis* DNA in first-catch female and male urine specimens from symptomatic and asymptomatic individuals prior to analysis with the Xpert CT/NG test and the Xpert TV test. **Intended User / Environment** The Xpert Urine Specimen Collection Kit is intended to be used by trained users.

We, as the manufacturer of the device take sole responsibility for and hereby declare that the above mentioned device meets the provisions of the following Regulation:

Regulation EU 2017/746 on *in vitro* Diagnostic Medical Devices	
Risk Class	A ☒ B☐ C☐ D☐
Classification Rule	Annex VIII, Rule: 5 (c) specimen receptacle
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 appliable

Certificate(s)	Not applicable

Signed on behalf of Cepheid by:

Signature

December 15, 2022
Date of Issue

Lena Kirsel
Senior Manager of Regulatory Affairs
Regulatory Affairs

Place of Issue: Solna, Sweden