

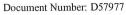
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EU DECLARATION OF CONFORMITY

	Cepheid 904 Caribbean Drive Sunnyvale, CA 94089
	USA
	Single Registration Number (SRN): US-MF-000010979
	Cepheid Europe SAS Vira Solelh
EC REP	81470 Maurens-Scopont
-	France
	Transc
	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⊠	В□	СП	D□
Classification Rule	Annex VIII,	Rule: 5 (c) speci	men receptacle	
Conformity Assessment Route	☐ Annex IX(I) Quality Management System			
	☐ Annex E	X(II) Technical D	ocumentation	
	☐ Annex X	Type Examinati	on	
	☐ Annex X	I Production Qual	lity Assurance	
	⊠ Annex II	& III (class A on	ly)	
Common Specification	Not applical	ole		
Notified Body	Not applical	ole		
Notified Body Number	Not appliabl	le		



December 15,2022



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Certificate(s)	Not applicable
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Signed on behalf of Cepheid by:

Signature

Lena Kirsel

Senior Manager of Regulatory Affairs

Regulatory Affairs

Place of Issue: Solna, Sweden