


EU DECLARATION OF CONFORMITY

	<p>Cepheid 904 Caribbean Drive Sunnyvale, CA 94089 USA</p> <p>Single Registration Number (SRN): US-MF-000010979</p>
EC REP	<p>Cepheid Europe SAS Vira Solelh 81470 Maurens-Scopont France</p> <p>Single Registration Number (SRN): FR-AR-000001368</p>
Device Trade Name	Xpert® Vaginal/Endocervical Specimen Collection Kit
Basic UDI-DI	081164701-SWAB/A-3H
REF	SWAB/A-50
Device Intended Purpose	<p>Intended Use The Xpert® Vaginal/Endocervical Specimen Collection Kit is designed to collect, preserve, and transport <i>Chlamydia trachomatis</i>, <i>Neisseria gonorrhoeae</i>, and <i>Trichomonas vaginalis</i> DNA in endocervical swab specimens (collected by a clinician) and patient collected vaginal swab specimens (collected in a clinical setting) from symptomatic and asymptomatic women prior to analysis with the Xpert CT/NG test or the Xpert TV test.</p> <p>Intended User / Environment The Xpert® Vaginal/Endocervical Specimen Collection Kit is intended to be used by trained users.</p>

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:

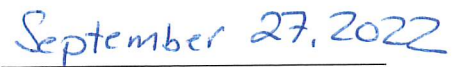
Regulation EU 2017/746 on <i>in vitro</i> Diagnostic Medical Devices	
Risk Class	A <input checked="" type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D <input type="checkbox"/>
Classification Rule	Annex VIII, Rule: 5 (c) specimen receptacle
Conformity Assessment Route	<input type="checkbox"/> Annex IX(I) Quality Management System <input type="checkbox"/> Annex IX(II) Technical Documentation <input type="checkbox"/> Annex X Type Examination <input type="checkbox"/> Annex XI Production Quality Assurance <input checked="" type="checkbox"/> Annex II & III (class A only)
Common Specification	Not applicable

Notified Body	Not applicable
Notified Body Number	Not applicable
Certificate(s)	Not applicable

Signed on behalf of Cepheid by:



Signature



Date of Issue

Lena Kirsel
Senior Manager of Regulatory Affairs
Regulatory Affairs

Place of Issue: Solna, Sweden