EU DECLARATION OF CONFORMITY

	Cepheid AB Röntgenvägen 5 SE-171 54, Solna Sweden Single Registration Number (SRN): SE-MF-000002020
Device Trade Name	Xpert® HPV v2
Basic UDI-DI	7332940-GXHPV2-NV
	GXHPV2-CE-10
Device Intended Purpose	The Xpert® HPV v2 test, performed on GeneXpert® systems, is an automated, qualitative, *in vitro* test for the detection of the E6/E7 region of the viral DNA genome from high risk Human Papillomavirus (HPV) in patient specimens. The test carries out multiplexed amplification of target DNA by real-time Polymerase Chain Reaction (PCR) of 14 high risk HPV types in a single analysis. Xpert HPV v2 specifically identifies types HPV 16 and HPV 18/45 in two distinct detection channels, and reports 11 other high risk types (31, 33, 35, 39, 51, 52, 56, 58, 59, 66 and 68) in a pooled result. Specimens are limited to cervical cells collected in PreservCyt® Solution (Hologic Corp.). Cervical specimens collected in PreservCyt Solution that have been pretreated with Glacial Acetic Acid (GAA) to lyse excess red blood cells for cytology review have also been validated for use with the Xpert HPV v2 test. • The Xpert HPV v2 test can be used with a Pap specimen to assess the presence or absence of genotypes 16 and 18/45 and other high risk HPV genotypes in adult females who are at increased risk of developing cervical cancer or presence of high-grade disease. • The Xpert HPV v2 test can be used as a first-line primary screening test to identify adult females who are at increased risk of developing cervical cancer or the presence of high-grade disease. This information, together with the physician's assessment of the patient's medical history, other risk factors, and

	professional guidelines, may be used to guide patient management. **Intended User/Environment** The Xpert HPV v2 test is intended to be performed by healthcare professionals trained on the use of the test. This test is for use in a laboratory environment.

We, as the manufacturer of the device(s) take sole responsibly for and hereby declare that the above mentioned device(s) meet(s) 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: 3 (a) and 3 (h)
Conformity Assessment Route	☒ Annex IX Quality Management System ☐ Annex IX Technical Documentation ☐ Annex X Type Examination ☐ Annex XI Production Quality Assurance ☐ Annex II & III (class A only)
Common Specification	N/A
Notified Body	BSI Group, The Netherlands B.V.
Notified Body Number	2797
Certificate(s)	IVDR 744859

Signed on behalf of Cepheid AB by:

2024-11-14

Signature | Date of Issue

Lena Kirsel
Senior Manager of Regulatory Affairs

Place of Issue: Solna, Sweden