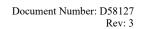




EU DECLARATION OF CONFORMITY

	Combaid AD		
	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		
REF	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		

Cepheid Public Date Printed: 11/14/2024 11:42:53 AM



p. 2 of 2



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	А	В□	C⊠	D□	
Classification Rule	Annex VIII, Rule: 3 (a) and 3 (h)				
Conformity Assessment Route					
	☐ Annex IX Technical Documentation				
	☐ Annex	X Type Examination	on		
	☐ Annex	XI Production Qua	lity Assurance		
	☐ Annex 1	II & III (class A on	ly)		
Common Specification	N/A				
Notified Body	BSI Group	, The Netherlands	B.V.		
Notified Body Number	2797				
Certificate(s)	IVDR 7448	859			

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