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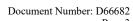


## **EU DECLARATION OF CONFORMITY**

Device Trade Name	Cepheid AB Röntgenvägen 5 SE-171 54 Solna Sweden Single Registration Number (SRN): SE-MF-000002020 Xpert® Xpress GBS
Basic UDI-DI	7332940-XPRSGBS-BG
REF	XPRSGBS-CE-10
Device Intended Purpose	Intended Use The Xpert® Xpress GBS test, performed on GeneXpert® systems, is an automated qualitative <i>in vitro</i> diagnostic real-time polymerase chain reaction (PCR) test for the detection of DNA from Group B <i>Streptococcus</i> (GBS). The test is performed using a dual vaginal/rectal swab specimen collected from pregnant patients during antepartum or intrapartum.  The Xpert Xpress GBS test is intended to aid in the detection of GBS colonization to identify candidates for antibiotic prophylaxis.  The Xpert Xpress GBS test does not provide antimicrobial susceptibility test results. Culture is necessary to obtain isolates to perform susceptibility testing as recommended for penicillinallergic patients.  Intended User / Environment The Xpert Xpress GBS test is intended to be performed by healthcare professionals trained on the use of the test. This test is for use in a laboratory or near-patient testing 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	АП	В□	C⊠	$\mathrm{D}\square$	
Classification Rule	Annex VIII, Rule: The Xpert® Xpress GBS test is covered by Rule 3 (c) and 3(e) and Rule 4(b) established in Regulation (EU) 2017/746. Therefore, device is a Class C device per Rule 3 (c, e) and a Near Patient Testing device per Rule 4 (b).				





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Conformity Assessment Route			
	☐ Annex X Type Examination		
	☐ Annex XI Production Quality Assurance		
	☐ Annex II & III (class A only)		
<b>Common Specification</b>	N/A		
<b>Notified Body</b>	BSI Group, The Netherlands B.V.		
Notified Body Number	2797		
Certificate(s)	IVDR 744859 (QMS certificate)		
	IVDR 793827 (Technical Documentation certificate)		
Signed on behalf of Cepheid AB	by:		
	2025-09-02		
Signature	Date of Issue		
Lena Kirsel	0 :		
Senior Manager, Regulatory Af	tairs		

Place of Issue: Solna, Sweden