EU DECLARATION OF CONFORMITY

	Cepheid AB Röntgenvägen 5 SE-171 54 Solna Sweden Single Registration Number (SRN): SE-MF-000002020
Device Trade Name	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 *in vitro* diagnostic real-time polymerase chain reaction (PCR) test for the detection of DNA from Group B *Streptococcus* (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 penicillin-allergic 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	A ☐	B☐	C☒	D☐
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).			

Conformity Assessment Route	☒ Annex IX(I) Quality Management System ☒ Annex IX(II) 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 (QMS certificate) IVDR 793827 (Technical Documentation certificate)

Signed on behalf of Cepheid AB by:

Signature
Lena Kirsel
Senior Manager, Regulatory Affairs

2025-09-02
Date of Issue

Place of Issue: Solna, Sweden