EU Certificate

Technical Documentation Assessment
REGULATION (EU) 2017/746 on In Vitro Diagnostic Medical Devices
Annex IX Chapter II

Registration No.:	IX 1545122-2
Manufacturer:	QIAGEN Sciences LLC 19300 Germantown Road Germantown MD 20874 USA
EUDAMED Single Registration No.:	US-MF-000014502
Classification:	C, Near-Patient Testing
General product group name:	IMMUNOCHEMISTRY (IMMUNOLOGY) IVR 0608 Devices intended to be used for screening, determination or monitoring of physiological markers W01020190 - OTHER SPECIFIC PROTEINS
Product name:	AmniSure ® ROM (Rupture of [fetal] Membranes) Test
Models and types:	FMRT-1-10-IVDR; FMRT-1-25-IVDR.
Basic UDI-DI:	4053228RAS0000000000001MP

The Notified Body hereby declares that the requirements of Annex IX, Chapter II, Section 4 and 5.1 / 5.2 of the REGULATION (EU) 2017/746 have been met for the listed products. The above named manufacturer has established and maintains a technical documentation defined by Annex IX, Chapter II, Section 4 and 5.1 / 5.2 of the aforementioned regulation. In addition to this certificate an EU quality management system certificate and for class D devices a batch verification is required before placing the listed products on the market.

Report No.:	1166920-40
Effective date:	2025-11-10
Expiry date:	2030-11-09
Issue date:	2025-11-10

Dr. Volker Schlueter
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

This certificate can be validated on https://www.certipedia.com

TÜV Rheinland LGA Products GmbH is a Notified Body according to REGULATION (EU) 2017/746 concerning medical devices with the identification number 0197.

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-IVDR-097

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Precisely Right.

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Intended use:	The AmniSure ROM (Rupture of [Fetal] Membranes) Test is a rapid, non-instrumented, qualitative immunochromatographic test for the in vitro detection of amniotic fluid in cervico-vaginal discharge of pregnant women using a sterile vaginal swab provided in the kit. The AmniSure ROM Test detects PAMG-1 protein marker of the amniotic fluid in cervico-vaginal discharge. The test is for use by healthcare professionals to aid in the detection of rupture of fetal membranes in pregnant women reporting signs, symptoms, or complaints suggestive of ROM
Authorized representative(s):	QIAGEN GmbH QIAGEN Strasse 1, 40724 Hilden, Germany DE-AR-000004971

Certificate history		
Revision:	Description:	Issue date:
0	Initial certification	2025-11-10