EU Certificate

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

Registration No.:	IX 1545122-1
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:	PartoSure Test
Models and types:	TTDT-1-20-IVDR
Basic UDI-DI:	4053228RPS0000000000001BT

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.:	1142788-260
Effective date:	2024-09-10
Expiry date:	2029-09-09
Issue date:	2024-09-10

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
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BS-MDR-091

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Intended use:	The PartoSure Test is a rapid, non-instrumented, qualitative immunochromatographic test for the in vitro detection of placental alpha microglobulin-1 (PAMG-1) in vaginal secretions of pregnant women using a sterile vaginal swab provided in the kit. The device is designed as an aid to rapidly assess the risk of preterm delivery in ≤7 days from the time of cervicovaginal sample collection in pregnant women with signs and symptoms of preterm labor, intact amniotic membranes, and minimal cervical dilatation (≤ 3 cm), sampled between 20 weeks, 0 days and 36 weeks, 6 days gestation.
Authorized representative(s):	QIAGEN GmbH QIAGEN Strasse 1, 40724 Hilden, Germany

Certificate history		
Revision:	Description:	Issue date:
0	Initial certification	2024-09-10

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