For electronic distribution only
Nur zur elektronischen Verbreitung

EU Quality Management System Certificate

We hereby certify the company

NG Biotech SAS
Atelier Relais Le Tremplin
Parc d'Act.de Courbouton Sect 1
35480 Guipry
France

the introduction and application of a quality management system in accordance with Annex IX, Chapter I and III of Regulation (EU) 2017/746 for conformity assessment.

An audit by mdc has proven that this quality management system meets the following requirements:

Annex IX – Chapter I (Quality Management System)

of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices.

Surveillance is carried out in accordance with Annex IX, Section 3 of Regulation (EU) 2017/746.

This certificate from mdc medical device certification GmbH (Notified Body 0483) consists of 2 pages. Details of the devices covered as well as further information and conditions are contained on the following pages.

Valid from	2025-03-27	Registration No.	D1395900023
Valid until	2030-03-26	Report No.	P23-01544-284893

Stuttgart, 2025-03-27

Notified Body

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-IVDR-098

Devices:

Rapid immunoassay intended to be used for detection of pregnancy or fertility testing

Risk class: B self-testing
IVR 0607 Devices intended to be used for detection of pregnancy or fertility testing

Notes:

For class A devices placed on the market in sterile condition the involvement of mdc is limited to the assessment of the aspects of manufacture concerned with securing and maintaining sterile conditions.

For devices for self-testing and near-patient testing the involvement of mdc additionally refers to the assessment of aspects according to Annex IX, Section 5.1.

For the placing on the market of class D devices an EU technical documentation assessment certificate is also required.