Certificate

mdc medical device certification GmbH
certifies that

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

with the locations listed in the attachment

for the scope

Design, Development, Manufacturing and Sales of
in vitro diagnostic devices based on lateral flow technology

has introduced and applies a

Quality Management System

The mdc audit has proven that this quality management system
meets all requirements of the following standard

EN ISO 13485

Medical devices – Quality management systems –
Requirements for regulatory purposes

EN ISO 13485:2016 + AC:2018 + A11:2021 - ISO 13485:2016

Valid from	2022-10-17
Valid until	2025-05-07
Registration no.	D1395900014
Report no.	P22-00166-249909
Stuttgart	2022-10-17

Head of Certification Body

medical device certification mdc

DAkkS Deutsche Akkreditierungsstelle D-ZM-16002-06-00

mdc medical device certification GmbH
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Attachment of the certificate		
No. D1395900014	date 2022-10-17	Page 1 of 1

Location	**Scope**
NG Biotech SAS Atelier Relais Le Tremplin Parc d'Act.de Courbouton Sect 1 35480 Guipry France	Design, Development, Manufacturing and Sales of in vitro diagnostic devices based on lateral flow technology
NG BIOTECH Parc d'Activité de Pelouaille 24 Secteur La Fosse Rouge 35480 Guipry-Messac France	Manufacturing and Storage of in vitro diagnostic devices based on lateral flow technology

Head of Certification Body

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