

EC Certificate

mdc medical device certification GmbH

Notified Body 0483
herewith certifies that

**NanoRepro AG
Untergasse 8
35037 Marburg
Germany**

for the scope

**immunochematographic rapid tests for self-testing
(see attachment)**

has introduced and applies a

Quality System

for the design, manufacture and final inspection.

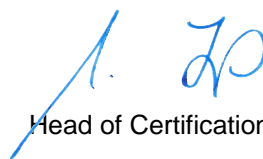
The mdc audit has proven that this quality system
meets all requirements according to

**Annex IV – excluding Section 4 and 6
of the Council Directive 98/79/EC**

of the European Parliament and of the Council of
27 October 1998 on in vitro diagnostic medical devices.

The surveillance will be held as specified in Annex IV, Section 5.

Valid from	2021-04-21
Valid until	2024-05-26
Registration no.	D1368900034
Report no.	P20-01004-203859
Stuttgart	2021-04-21



Head of Certification Body



Attachment of the certificate

No. D1368900034

Date 2021-04-21

Page 1 of 2

Product category	Product	Class
Immunochemical rapid tests for self-testing to detect allergies	AllergoCHECK REF 860000S, 850250, 860100S, 860400S ZuhauseTEST Allergie REF 860200S MilchCHECK REF 450000 MilkCHECK REF 457000, 450250 ZuhauseTEST Milcheiweißallergie REF 454000	Self-testing not Annex II
Immunochemical rapid test for self-testing to detect gluten intolerance	GlutenCHECK REF 420000, 400100, 400480, 400620, 400630, 400640, 400490, 410250 CeliacDetect REF 400444 ZuhauseTEST Zöliakie REF 400250 Veroval SELBST-TEST Gluten Intoleranz REF 924202, 924203, 924205, 924207	Self-testing not Annex II
Immunochemical rapid test for self-testing to detect Helicobacter pylori	Heli-C-CHECK REF 920000, 900490, 900670, 900680, 900250 ZuhauseTEST Gesunder Magen REF 900350 Veroval SELBST-TEST Magen-Vorsorge REF 924002, 924007	Self-testing not Annex II
Immunochemical rapid test for self-testing to detect iron deficiency	EisenCHECK REF 360000 FerritinCHECK REF 360100, 360400 ZuhauseTEST Eisenmangel REF 360200 Veroval SELBST-TEST Eisenmangel REF 924102, 924103, 924105, 924107	Self-testing not Annex II
Immunochemical rapid test for self-testing for the determination of male fertility	FertiQUICK REF 820000, 800870, 800880, 800890, 800250 ZuhauseTEST Fertilität REF 800400 Veroval SELBST-TEST Zeugungsfähigkeit REF 924362, 924365, 924367	Self-testing not Annex II
Immunochemical rapid test for self-testing to detect the risk of colon cancer	FOBCHECK REF 700400 ZuhauseTEST Gesunder Darm REF 700700	Self-testing not Annex II



 Head of Certification Body



Attachment of the certificate

No. D1368900034

Date 2021-04-21

Page 2 of 2

Product category	Product	Class
Immunochromatographic rapid test for self-testing to detect defective thyroid function	TSHCHECK REF 780000 ZuhauseTEST Schilddrüse REF 782000 Veroval ZELFTEST Schilddrüse REF 924415	Self-testing not Annex II
Immunochromatographic rapid test for self-testing to detect the onset of menopause	MenoQUICK REF 300000, 300690, 300250 ZuhauseTEST Menopause REF 300300 KlimaSei Test menopauzy REF 300530	Self-testing not Annex II
Immunochromatographic rapid test for self-testing to detect vaginal fungal infection	VagiQUICK REF 500000, 501250 ZuhauseTEST Vaginalpilz REF 500250	Self-testing not Annex II
Immunochromatographic rapid test for self-testing to detect the onset of ovulation	OvuQUICK REF 100000,120000B, OvuQUICK midstream REF 121000B, 100100 ZuhauseTEST Ovulation REF 100400B, 100500 safe&easy Ovulationstest REF 100200B Ari-T Test de ovulacao REF 100300	Self-testing not Annex II
Immunochromatographic rapid test for self-testing to detect pregnancy	GraviQUICK Schwangerschafts-Schnelltest REF 210160B, 210100B, 200000, 210160BC Schwangerschafts Schnelltest Aristo REF 200150	Self-testing not Annex II
Immunochromatographic rapid test for self-testing to detect pregnancy in early stage	GraviQUICK Schwangerschafts-Frühtest REF 200580B, 200590B, 200500, 210600 GraviQUICK früh midstream REF 200900 ZuhauseTEST Schwangerschaft früh REF 200700, 200800 Ari-T Test de gravidez REF 200520 Schwangerschafts Frühtest Aristo REF 200510	Self-testing not Annex II





 Head of Certification Body