EG-Konformitätserklärung
CE-Declaration de Conformité / EC-Declaration of Conformity

CE

Testreagenzien Anti-Salmonella O-Gruppen-Pools
Réactifs de test Pools anti-salmonelles du groupe O
Test Reagents Anti-Salmonella O-group Pools

Wir / Nous / We

sifin diagnostics gmbh
Berliner Allee 317-321, 13088 Berlin, Germany
phone +49-30-700-144-0, fax +49-30-700-144-30, info@sifin.de, www.sifin.de

erklären in eigener Verantwortung, dass
déclarons sous notre propre responsabilité que / declare on our own responsibility that

die Medizinprodukte (IVD):
les dispositifs médical (IVD) :
the medical devices (IVD):

Testreagenzien Anti-Salmonella O-Gruppen-Pools
Réactifs de test Pools anti-salmonelles du groupe O
Test Reagents Anti-Salmonella O-group Pools

TR1151	Anti-Salmonella OMA
TR1151-01	Anti-Salmonella OMA
TR1161	Anti-Salmonella OMB
TR1161-01	Anti-Salmonella OMB
TR1170	Anti-Salmonella OMC
TR1171	Anti-Salmonella OMD
TR1172	Anti-Salmonella OME
TR1173	Anti-Salmonella OMF
TR1174	Anti-Salmonella OMG

Sonstige Produkte
Autres dispositifs/Other devices

allen Anforderungen der Richtlinie 98/79/EG entsprechen.
remplirent toutes les exigences de la Directive 98/79/EG qui le concernait.
meet all the provisions of the Directive 98/79/EG which apply to it.

Angewandte harmonisierte Normen:
Normes nationales appliqués:
Applied national standards:

DIN EN ISO 13485:2016,
DIN EN 13612:2002,
DIN EN 13641:2002,
DIN EN ISO 14971:2013,
DIN EN ISO 15223-1:2021,
DIN EN ISO 18113-1:2013,
DIN EN ISO 18113-2:2013,
DIN EN ISO 23640:2015

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Testreagenzien Anti-Salmonella O-Gruppen-Pools

Réactifs de test Pools anti-salmonelles du groupe O

Test Reagents Anti-Salmonella O-group Pools

Konformitätsbewertungsverfahren: Procèdure d'évaluation de la conformità: Conformity assessment procedure:	Anhang III Annexe III Annex III
Gültig bis: Valable jusqu'au: Valid until:	2027-05-25

Berlin, 25.01.2022

Dr. Kathrin Landgrebe
Sicherheitsbeauftragte für Medizinprodukte
Agent de sécurité / Safety Officer

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Testreagenzien Anti-Salmonella O, Vi

Réactifs de test Anti-Salmonella O, Vi
Test Reagents Anti-Salmonella O, Vi

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les dispositifs médical (IVD) :
the medical devices (IVD):

Testreagenzien Anti-Salmonella O, Vi
Réactifs de test Anti-Salmonella O, Vi
Test Reagents Anti-Salmonella O, Vi

TR1201	Anti-Salmonella Group B
TR1201-01	Anti-Salmonella Group B
TR1202	Anti-Salmonella Group C
TR1203	Anti-Salmonella Group D
TR1203-01	Anti-Salmonella Group D
TR1204	Anti-Salmonella Group E
TR1301	Anti-Salmonella O:2
TR1302	Anti-Salmonella O:4
TR1302-01	Anti-Salmonella O:4
TR1303	Anti-Salmonella O:5
TR1303-01	Anti-Salmonella O:5
TR1304	Anti-Salmonella O:6_1
TR1305	Anti-Salmonella O:7
TR1306	Anti-Salmonella O:8
TR1307	Anti-Salmonella O:9
TR1307-01	Anti-Salmonella O:9
TR1308	Anti-Salmonella O:10
TR1323	Anti-Salmonella O:11
TR1325	Anti-Salmonella O:13
TR1309	Anti-Salmonella O:14
TR1310	Anti-Salmonella O:15
TR1328	Anti-Salmonella O:16
TR1329	Anti-Salmonella O:17
TS1330	Anti-Salmonella O:18
TR1311	Anti-Salmonella O:19
TR1312	Anti-Salmonella O:20
TR1331	Anti-Salmonella O:21

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Testreagenzien Anti-Salmonella O, Vi

Réactifs de test Anti-Salmonella O, Vi

Test Reagents Anti-Salmonella O, Vi

TS1332	Anti-Salmonella O:22
TR1335	Anti-Salmonella O:25
TR1313	Anti-Salmonella O:27
TR1336	Anti-Salmonella O:28
TR1339	Anti-Salmonella O:30
TR1314	Anti-Salmonella O:34
TR1341	Anti-Salmonella O:35
TR1344	Anti-Salmonella O:38
TR1345	Anti-Salmonella O:39
TR1346	Anti-Salmonella O:40
TR1347	Anti-Salmonella O:41
TR1348	Anti-Salmonella O:42
TR1349	Anti-Salmonella O:43
TR1350	Anti-Salmonella O:44
TR1351	Anti-Salmonella O:45
TR1315	Anti-Salmonella O:46
TR1353	Anti-Salmonella O:47
TR1354	Anti-Salmonella O:48
TR1355	Anti-Salmonella O:50
TR1356	Anti-Salmonella O:51
TR1357	Anti-Salmonella O:52
TR1358	Anti-Salmonella O:53
TR1359	Anti-Salmonella O:54
TR1360	Anti-Salmonella O:55
TR1361	Anti-Salmonella O:56
TR1362	Anti-Salmonella O:57
TR1363	Anti-Salmonella O:58
TR1364	Anti-Salmonella O:59
TR1365	Anti-Salmonella O:60
TR1366	Anti-Salmonella O:61
TR1367	Anti-Salmonella O:62
TR1368	Anti-Salmonella O:63
TR1369	Anti-Salmonella O:65
TR1370	Anti-Salmonella O:66
TR1371	Anti-Salmonella O:67
TR1316	Anti-Salmonella Vi

Sonstige Produkte
Autres dispositifs/Other devices

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meet all the provisions of the Directive 98/79/EG which apply to it.

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Testreagenzien Anti-Salmonella O, Vi

Réactifs de test Anti-Salmonella O, Vi

Test Reagents Anti-Salmonella O, Vi

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Gültig bis: Valable jusqu'au: Valid until:	2027-05-25

Berlin, 25.01.2022

Dr. Kathrin Landgrebe
Sicherheitsbeauftragte für Medizinprodukte
Agent de sécurité / Safety Officer

Certificate

mdc medical device certification GmbH
certifies that

sifin

sifin diagnostics gmbh
Berliner Allee 317-321
13088 Berlin
Germany

for the scope

development, manufacturing and distribution of
in vitro diagnostic medical devices for the product groups:
blood grouping, bacteriological test reagents and culture media as well as
manufacturing of raw materials for manufacturing of
in vitro diagnostic medical devices

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:2016 - ISO 13485:2016

Valid from	2021-10-23
Valid until	2024-10-22
Registration no.	D1058700050
Report no.	P21-00883-206453
Stuttgart	2021-07-23

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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Fax: +49-(0)711-253597-10
Internet: http://www.mdc-ce.de