

# 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



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Internet: <http://www.mdc-ce.de>



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



**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
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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:	DIN EN ISO 13485:2016,
Normes nationales appliqués:	DIN EN 13612:2002,
Applied national standards:	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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Test Reagents Anti-Salmonella O-group Pools

Konformitätsbewertungsverfahren: Anhang III  
Procédure d'évaluation de la conformité: Annexe III  
Conformity assessment procedure: Annex III

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

Berlin, 25.01.2022

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



**EG-Konformitätserklärung**  
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**Testreagenzien Anti-Shigella**  
Réactifs de test Anti-Shigella  
Test Reagents Anti-Shigella

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

Testreagenzien Anti-Shigella  
Réactifs de test Anti-Shigella  
Test Reagents Anti-Shigella

TR1811	Anti-Shigella I
TR1811-01	Anti-Shigella I
TS1821	Anti-Shigella II
TS1821-01	Anti-Shigella II
TS1831	Anti-Shigella III
TS1901	Anti-Shigella flexneri
TS2001	Anti-Shigella dysenteriae type 1
TS2002	Anti-Shigella dysenteriae type 2
TS2003	Anti-Shigella flexneri type 1
TS2004	Anti-Shigella flexneri type 2
TS2005	Anti-Shigella flexneri type 3
TS2006	Anti-Shigella flexneri type 4
TS2007	Anti-Shigella flexneri type 5
TS2008	Anti-Shigella flexneri type 6
TS2009	Anti-Shigella flexneri group 3,4 (y)
TS2010	Anti-Shigella flexneri group 6
TS2011	Anti-Shigella flexneri group 7,8 (x)
TR2012	Anti-Shigella sonnei S-form (phase I)
TR2013	Anti-Shigella sonnei F-form (phase II)
TR2014	Anti-Shigella sonnei S-form and F-form (phase II and phase II)

Sonstige Produkte  
Autres dispositifs/Other devices



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**Testreagenzien Anti-Shigella**  
**Réactifs de test Anti-Shigella**  
**Test Reagents Anti-Shigella**

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