ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-IVDR-099

Product Service

EU Quality Management System Certificate (IVDR)

Pursuant to Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices, Annex IX Chapters I and III (Class C and B Devices excluding self-/near-patient-testing and Companion Diagnostics)

No. V12 071067 0008 Rev. 00

Manufacturer: **Liofilchem S.r.l.**
Via Scozia
64026 Roseto degli Abruzzi (TE)
ITALY

SRN Manufacturer: Not available at the issuance date of this certificate

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (8) of the Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices. Details on devices covered by the quality management system are described on the following page(s).
The Report referenced below summarizes the result of the assessment and includes reference to relevant CS, harmonized standards, audit and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.
The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment includes an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:V12 071067 0008 Rev. 00

Report No.: ITA1674857

Valid from: 2022-07-25

Valid until: 2027-07-24

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2022-07-25

Digitally signed by Ceaicovschi Tudor
Date: 2023.02.06 10:25:57 EET
Reason: MoldSign Signature
Location: Moldova

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-IVDR-099

TÜV SÜD Product Service

EU Quality Management System Certificate (IVDR)

Pursuant to Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices, Annex IX Chapters I and III (Class C and B Devices excluding self-/near-patient-testing and Companion Diagnostics)

No. V12 071067 0008 Rev. 00

Classification:	B
Device Group:	W0104 - MICROBIOLOGY (CULTURE)
Intended Purpose:	IVR 0505 - Devices intended to be used to grow/isolate/identify and handle infectious agents

Classification:	B
Device Group:	W0104 - MICROBIOLOGY (CULTURE)
Intended Purpose:	IVR 0503 - Devices intended to be used to detect the presence of, or exposure to an infectious agent including sexually transmitted agents

Classification:	C
Device Group:	W0104 - MICROBIOLOGY (CULTURE)
IVP Code:	IVP 3002 - In vitro diagnostic devices which require knowledge regarding biochemistry
Intended Purpose:	IVR 0505 - Devices intended to be used to grow/isolate/identify and handle infectious agents

The validity of this certificate depends on conditions and/or is limited to the following:	\

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

Product Service

Certificate

No. Q5 071067 0006 Rev. 02

Holder of Certificate: **Liofilchem S.r.l.**
Via Scozia
64026 Roseto degli Abruzzi (TE)
ITALY

Certification Mark:

TÜV SÜD EN ISO 13485 tuvsud.com/ps-cert

Scope of Certificate: **Design and development, production and sales of in-vitro diagnostic medical devices: culture media for microbiology, identification and susceptibility testing systems, Minimum Inhibitory Concentration test strips, antibiotic discs, kits for plasma protein determination. Distribution of other in-vitro diagnostic medical devices.**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 071067 0006 Rev. 02

Report No.: ITA 1775694

Valid from: 2021-12-19
Valid until: 2024-12-18

Date, 2021-12-10

Christoph Dicks
Head of Certification/Notified Body

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DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 071067 0006 Rev. 02

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

Liofilchem S.r.l.
Via Scozia, 64026 Roseto degli Abruzzi (TE), ITALY

Production and sales of in-vitro diagnostic medical devices: dehydrated and ready-to-use culture media for microbiology.

Liofilchem S.r.l.
Via Uruguay, 64026 Roseto degli Abruzzi (TE), ITALY

Design and development, production and sales of in-vitro:diagnostic medical devices: ready-to-use culture media for microbiology, reagents and supplements, microbial identification and antimicrobial susceptibility testing systems, Minimum Inhibitory Concentration test strips, antibiotic discs, plasma protein determination kits. Distribution of other in-vitro diagnostic medical devices. Design and development and distribution of dehydrated culture media for microbiology.

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ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

Product Service

C E R T I F I C A T O

N°Q5 071067 0006 Rev. 02

Titolare del certificato: **Liofilchem S.r.l.**
Via Scozia
64026 Roseto degli Abruzzi (TE)
ITALIA

Marchio di certificazione:

TÜV SÜD EN ISO 13485 tuvsud.com/ps-cert

Campo di applicazione:

Progettazione e sviluppo, produzione e vendita di dispositivi medico diagnostici in-vitro: terreni di coltura per microbiologia, sistemi di identificazione e antibiogramma, strip per determinazione della Minima Concentrazione Inibente, dischetti antibiotici, kit per la determinazione di plasmaproteine. Distribuzione di altri dispositivi medico diagnostici in-vitro.

L'Organismo di Certificazione TÜV SÜD Product Service GmbH certifica che la società sopramenzionata ha istituito e mantiene un sistema di gestione qualità conforme ai requisiti della(e) norma(e) elencata(e). Tutti i requisiti applicabili del Regolamento "Testing and Certification" del gruppo TÜV SÜD devono essere rispettati. Per dettagli e validità del certificato vedi: www.tuvsud.com/ps-cert?q=cert:Q5 071067 0006 Rev.

N° del rapporto: ITA 1775694

Valido da: 2021-12-19
Valido fino al: 2024-12-18

Data, 2021-12-10

Christoph Dicks
Head of Certification/Notified Body

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DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

C E R T I F I C A T O

N°Q5 071067 0006 Rev. 02

Norma(e) applicata(e): EN ISO 13485:2016
Dispositivi medicali – Sistemi di gestione qualità - Requisiti per scopi regolamentari
(ISO 13485:2016)
DIN EN ISO 13485:2016

Stabilimento(i):

Liofilchem S.r.l.
Via Scozia, 64026 Roseto degli Abruzzi (TE), ITALIA

Produzione e vendita di dispositivi medico diagnostici in-vitro: terreni di coltura disidratati e terreni di coltura pronti per microbiologia.

Liofilchem S.r.l.
Via Uruguay, 64026 Roseto degli Abruzzi (TE), ITALIA

Progettazione e sviluppo, produzione e vendita di dispositivi medico diagnostici in-vitro: terreni di coltura pronti per microbiologia, reagenti e supplementi, sistemi di identificazione e antibiogramma, strip per determinazione della Minima Concentrazione Inibente, dischetti antibiotici, kit per la determinazione di plasmaproteine. Distribuzione di altri dispositivi medico diagnostici in-vitro. Progettazione e sviluppo e commercializzazione di terreni di coltura disidratati per microbiologia.

/

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Certificate

mdc medical device certification GmbH
certifies that

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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
Kriegerstraße 6
D-70191 Stuttgart, Germany
Phone: +49-(0)711-253597-0
Fax: +49-(0)711-253597-10
Internet: http://www.mdc-ce.de

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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

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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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EG-Konformitätserklärung

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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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EG-Konformitätserklärung

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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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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, 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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EG-Konformitätserklärung

CE-Declaration de Conformité / EC-Declaration of Conformity

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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

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.

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Testreagenzien Anti-Salmonella O, Vi

Réactifs de test Anti-Salmonella O, Vi

Test Reagents Anti-Salmonella O, Vi

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
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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EG-Konformitätserklärung

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Testreagenzien Anti-Salmonella H-Phasen-Pools

Réactifs pour tests Anti-Salmonella H-Phase Pools
Test Reagents Anti-Salmonella H-Phases pools

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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 H-Phasen-Pools
Réactifs pour tests Anti-Salmonella H-Phase Pools
Test Reagents Anti-Salmonella H-Phases pools

TR1181	Anti-Salmonella HMA
TR1181-01	Anti-Salmonella HMA
TR1183	Anti-Salmonella HMB
TR1183-01	Anti-Salmonella HMB
TR1185	Anti-Salmonella HMC
TR1185-01	Anti-Salmonella HMC

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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EG-Konformitätserklärung

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Testreagenzien Anti-Salmonella H-Phasen-Pools

Réactifs pour tests Anti-Salmonella H-Phase Pools

Test Reagents Anti-Salmonella H-Phases 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

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Testreagenzien Anti-Salmonella H

Réactifs pour tests Anti-Salmonella H
Test Reagents Anti-Salmonella H

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

Testreagenzien Anti-Salmonella H
Réactifs pour tests Anti-Salmonella H
Test Reagents Anti-Salmonella H

TR1401	Anti-Salmonella H:a
TR1402	Anti-Salmonella H:b
TR1403	Anti-Salmonella H:c
TR1404	Anti-Salmonella H:d
TR1405	Anti-Salmonella H:E
TR1405-01	Anti-Salmonella H:E
TR1407	Anti-Salmonella H:f
TR1406	Anti-Salmonella H:g
TR1406-01	Anti-Salmonella H:g
TR1408	Anti-Salmonella H:g,m
TR1408-01	Anti-Salmonella H:g,m
TR1409	Anti-Salmonella H:h
TR1410	Anti-Salmonella H:i
TR1410-01	Anti-Salmonella H:i
TR1411	Anti-Salmonella H:k
TR1412	Anti-Salmonella H:L
TR1412-01	Anti-Salmonella H:L
TS1413	Anti-Salmonella H:m
TR1438	Anti-Salmonella H:n
TS1414	Anti-Salmonella H:p
TS1415	Anti-Salmonella H:q
TR1416	Anti-Salmonella H:r
TS1417	Anti-Salmonella H:s
TS1418	Anti-Salmonella H:t
TS1419	Anti-Salmonella H:u
TS1420	Anti-Salmonella H:v
TS1421	Anti-Salmonella H:w
TS1422	Anti-Salmonella H:x
TR1423	Anti-Salmonella H:y

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Testreagenzien Anti-Salmonella H
Réactifs pour tests Anti-Salmonella H
Test Reagents Anti-Salmonella H

TR1424	Anti-Salmonella H:z
TS1425	Anti-Salmonella H:z_4,z_{23}
TS1426	Anti-Salmonella H:z_6
TR1427	Anti-Salmonella H:z_{10}
TS1428	Anti-Salmonella H:z_{15}
TR1440	Anti-Salmonella H:z_{23}
TS1429	Anti-Salmonella H:z_{24}
TS1449	Anti-Salmonella H:z_{28}
TS1430	Anti-Salmonella H:z_{29}
TS1431	Anti-Salmonella H:z_{32}
TR1445	Anti-Salmonella H:z_{35}
TR1447	Anti-Salmonella H:z_{38}
TR1448	Anti-Salmonella H:z_{41}
TR1437	Anti-Salmonella H:1
TR1437-01	Anti-Salmonella H:1
TR1433	Anti-Salmonella H:2
TR1433-01	Anti-Salmonella H:2
TS1434	Anti-Salmonella H:5
TR1435	Anti-Salmonella H:6
TS1436	Anti-Salmonella H:7

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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EG-Konformitätserklärung

CE-Declaration de Conformité / EC-Declaration of Conformity

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Testreagenzien Anti-Salmonella H

Réactifs pour tests Anti-Salmonella H

Test Reagents Anti-Salmonella H

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