MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

CERTIFICATE

No. QS6 071067 0007 Rev. 00

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

Certification Mark:

Scope of Certificate: **Design, Development, Manufacture and Distribution of In-Vitro Diagnostic Medical Devices: Microbial Identification and Antimicrobial Susceptibility Testing Systems, Antibiotic Minimum Inhibitory Concentration Test Strips, Antibiotic Discs, Dehydrated and Ready-To-Use Culture Media, Plasma Protein Determination Kits**

Standard(s): **ISO 13485:2016**

Regulatory Authority(ies): **Australia TGA, Brazil ANVISA, Health Canada, USA FDA, MHLW / PMDA. See attached for listing of specific regulatory requirements.**

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. Validity of this certificate can be obtained by visiting the website https://www.tuev-sued.de/product-testing/certificates

TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

DUNS No: **43-534-2134**

Effective Date: **2019-03-11**

Expiry Date: **2022-03-10**

Date of Issue: 2019-03-18

(Arie Henkin)
Manager, Certification Body MHS

TÜV®

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT
TÜV SÜD

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

CERTIFICATE

No. QS6 071067 0007 Rev. 00

Regulatory Requirements: **Audit/Certification Criteria**

Australia
Therapeutic Goods (Medical Devices) Regulations 2002
- Schedule 3, Part 1

Brazil
- RDC ANVISA n. 16/2013
- RDC ANVISA n. 23/2012
- RDC ANVISA n. 67/2009

Canada
- Medical Device Regulations SOR/98-282, Part 1

United States
- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807
- 21 CFR Part 820
- 21 CFR Part 821

Japan
- MHLW Ministerial Ordinance 169, Article 4 to Article 68
- PMD Act

Facility(ies):

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

Liofilchem S.r.l.
Contrada Piane Vomano, Traversa di Via Grecia, 64026 Roseto degli Abruzzi (TE), ITALY

Date of Issue: 2019-03-18

(Arie Henkin)
Manager, Certification Body MHS

TÜV SÜD America Inc. • 10 Centennial Drive Ste 207 • Peabody, MA 01960 USA • www.tuvsud.com

TÜV®

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

CERTIFICATE

No. QS6 071067 0007 Rev. 00

Facility Scopes:

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

Production of In-Vitro Diagnostic Medical Devices: Culture Media for Bacteriology
DUNS No: 43-534-2134

Liofilchem S.r.l.
Contrada Piane Vomano, Traversa di Via Grecia, 64026 Roseto degli Abruzzi (TE), Italy

Design and Development, Production and Sale of In-Vitro Diagnostic Medical Devices: Culture Media for Bacteriology, Identification and Susceptibility Testing Systems, Kits for Plasma Protein Determination; Distribution of Other In-Vitro Diagnostic Medical Devices
DUNS No: 43-534-2134

Date of issue: 2019-03-18

(Arie Henkin)
Manager, Certification Body MHS

TÜV SÜD America Inc. • 10 Centennial Drive Ste 207 • Peabody, MA 01960 USA • www.tuvsud.com

TÜV®

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

TÜV SÜD Italia

CERTIFICATO

Nr. 50 100 11497 - Rev. 003

Si attesta che / *This is to certify that*

IL SISTEMA QUALITÀ DI
THE QUALITY SYSTEM OF

LIOFILCHEM S.r.l.

SEDE LEGALE E OPERATIVA:
REGISTERED OFFICE AND OPERATIONAL SITE:

VIA SCOZIA SNC - ZONA INDUSTRIALE
I-64026 ROSETO DEGLI ABRUZZI (TE)

SEDE OPERATIVA:
OPERATIONAL SITE:

CONTRADA PIANE VOMANO – TRAVERSA DI VIA GRECIA
I-64026 ROSETO DEGLI ABRUZZI (TE)

È CONFORME AI REQUISITI DELLA NORMA
HAS BEEN FOUND TO COMPLY WITH THE REQUIREMENTS OF

UNI EN ISO 9001:2015

QUESTO CERTIFICATO È VALIDO PER IL SEGUENTE CAMPO DI APPLICAZIONE
THIS CERTIFICATE IS VALID FOR THE FOLLOWING SCOPE

Progettazione e sviluppo, produzione e commercializzazione di dispositivi medico diagnostici in-vitro: terreni di coltura per batteriologia, sistemi di identificazione e antibiogramma, kit per la determinazione di plasmaproteine (IAF 12, 29)

Design and development, production and sale of in-vitro diagnostic medical devices: culture media for bacteriology, identification and susceptibility testing systems, kits for plasma protein determination (IAF 12, 29)

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 049A

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

Per l'Organismo di Certificazione
For the Certification Body
TÜV Italia S.r.l.

Validità / *Validity*

Dal / From: **2019-02-11**

Al / To: **2022-02-10**

Data emissione / *Issuing Date*

2019-02-11

Andrea Coscia
Direttore Divisione Business Assurance

PRIMA CERTIFICAZIONE / *FIRST CERTIFICATION:* 2012-09-25

"LA VALIDITÀ DEL PRESENTE CERTIFICATO È SUBORDINATA A SORVEGLIANZA PERIODICA A 12 MESI E AL RIESAME COMPLETO DEL SISTEMA DI GESTIONE AZIENDALE CON PERIODICITÀ TRIENNALE"

"THE VALIDITY OF THE PRESENT CERTIFICATE DEPENDS ON THE ANNUAL SURVEILLANCE EVERY 12 MONTHS AND ON THE COMPLETE REVIEW OF COMPANY'S MANAGEMENT SYSTEM AFTER THREE-YEARS"

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

CERTIFICATO
N° Q5 071067 0006 Rev. 00

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

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

Liofilchem S.r.l.
Contrada Piane Vomano,Traversa di Via Grecia,
64026 Roseto degli Abruzzi (TE), ITALIA

Marchio di certificazione:

Campo di applicazione: **Progettazione e sviluppo, produzione e commercializzazione di dispositivi medico diagnostici in-vitro: terreni di coltura per batteriologia, sistemi di identificazione e antibiogramma, kit per la determinazione di plasmaproteine. Distribuzione di altri dispositivi medico diagnostici in-vitro**

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

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). Vedere anche note sul retro.

N° del rapporto: ITA1070742

Valido da: 2018-12-19
Valido fino al: 2021-12-18

Data, 2018-12-19

Stefan Preiß

Traduzione per scopi informativi. La sola versione inglese (tedesca) è legalmente impegnativa.

TÜV

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

TÜV SÜD
Product Service

Certificate

No. Q5 071067 0006 Rev. 00

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

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

Liofilchem S.r.l.
Contrada Piane Vomano, Traversa di Via Grecia, 64026 Roseto degli Abruzzi (TE), ITALY

Certification Mark:

TÜV SÜD
tuv-sud.com/ps-cert

Scope of Certificate: **Design and development, production and sale of in-vitro diagnostic medical devices: culture media for bacteriology, identification and susceptibility testing systems, kits for plasma protein determination. Distribution of other in-vitro diagnostic medical devices**

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

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). See also notes overleaf.

Report No.: ITA1070742

Valid from: 2018-12-19
Valid until: 2021-12-18

I. Preiß

Stefan Preiß

Date, 2018-12-19

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV

Liofilchem®

DICHIARAZIONE DI CONFORMITÀ CE / EC DECLARATION OF CONFORMITY

DICHIARAZIONE DI CONFORMITÀ CE

La società Liofilchem® S.r.l., con Sede Legale in Via Scozia, 64026 Roseto degli Abruzzi (TE) Italia, in qualità di fabbricante del dispositivo medico-diagnostico *in vitro* elencato nella tabella allegata Revisione 32.1 del 07.06.2017

dichiara sotto la propria responsabilità

1. che il dispositivo sopra indicato soddisfa tutte le disposizioni applicabili della Direttiva 98/79/CE (Allegato III) recepita nella Legislazione Italiana dal Decreto Legislativo n° 332 del 8 settembre 2000;
2. che il dispositivo in oggetto non è incluso nell'Allegato II, lista A e B della Direttiva 98/79/CE
3. che la documentazione tecnica di cui all'allegato III della direttiva Direttiva 98/79/CE è a disposizione delle autorità nazionali presso la sua sede e sarà conservata per 5 anni dall'ultima data di fabbricazione del prodotto;
4. che il processo di fabbricazione segue adeguati principi di assicurazione della qualità;
5. di aver attivato e di mantenere aggiornato, un sistema di sorveglianza post-produzione per il monitoraggio dei prodotti;
6. che il dispositivo in oggetto è stato messo in commercio munito di marcatura CE.

EC DECLARATION OF CONFORMITY

The company Liofilchem® S.r.l., registered office in Via Scozia, 64026 Roseto degli Abruzzi (TE) Italy, as a manufacturer of the in vitro medical-diagnostic device listed in the attached table, Revision 32.1 of 07.06.2017

hereby certifies under its own responsibility

1. that the above mentioned device complies with all the applicable provisions of Directive 98/79/EC (Annex III) and its relevant transposition into national law;
2. the above mentioned is not included in Annex II , List A and B of Directive 98/79/EC;
3. that the technical documentation referred to at Annex III of the Directive 98/79/EC is available for the national authorities in its facility and that this documentation shall be kept for 5 years after the last product has been manufactured;
4. that the manufacturing process follows suitable principles of quality assurance;
5. that, has implemented and keep up to date, a post-production surveillance system for monitoring the products;
6. that the device in question, was introduced into the market provided with CE mark.

Roseto, 07.06.2017

Direttore Tecnico/ Technical Director
Dott. Silvio Brocco

Certificate

mdc medical device certification GmbH
certifies that

Biolife Italiana Srl
Viale Monza 272
20128 Milano
Italy

for the scope

design, manufacturing and distribution of in vitro diagnostic 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	2018-08-29
Valid until	2021-08-29
Registration no.	D2001500012
Report no.	P18-00838-123320
Stuttgart	2018-08-29

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

For electronic publication only

Certificate

mdc medical device certification GmbH
certifies that

Biolife Italiana Srl
Viale Monza 272
20128 Milano
Italy

for the scope

design, manufacturing and distribution of in vitro diagnostic 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 9001

Quality management systems – Requirements

(ISO 9001:2015)

Valid from	2018-08-29
Valid until	2021-08-29
Registration no.	D2001500013
Report no.	P18-00838-123323
Stuttgart	2018-08-29

Head of Certification Body

medical device certification mdc

DAkkS Deutsche Akkreditierungsstelle D-ZM-16002-01-01

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

Biolife Italiana S.r.l

Viale Monza, 272
20128 Milano - Italy
Tel +39 02.25.209.1
Fax +39 02.25.76.428
info@biolifeitaliana.it
www.biolifeitaliana.it

Certified Quality System
ISO 13485:2016
Cert. n° D2001500012
ISO 9001:2015
Cert. n° D2001500013

DICHIARAZIONE CE DI CONFORMITA'

EC Declaration of Conformity

Con il presente documento, Biolife Italiana S.r.l. con sede legale in Viale Monza 272 - 20128 Milano dichiara, sotto la propria responsabilità, che i prodotti sotto elencati, classificati come Dispositivi Medici Diagnostici In Vitro (IVD) sono conformi ai requisiti essenziali della Direttiva Europea 98/79/EC sulla diagnostica in vitro e sono in accordo con l'Allegato III della Direttiva medesima.
La dichiarazione di Conformità è redatta secondo la Direttiva Europea 98/79/EC Allegato III.

Validità: questo documento è valido per 3 anni dalla data di emissione ed è revisionato su base annuale.

With this document, Biolife Italiana S.r.l. with legal address in Viale Monza 272 - 20128 Milan declares, under its own responsibility, that the products listed below, classified as In Vitro Diagnostic Medical Devices (IVD), comply with the Essential requirements of the European Directive 98/79/EC on in vitro diagnostics and are in accordance with Annex III of the Directive itself.
The declaration of conformity is drafted according to the European Directive 98/79/EC Annex III.

Validity: this document is valid for 3 years from the date of issue and is revised on an annual basis.

Biolife Italiana Srl
Dr Massimo Brunelli

Direttore Generale/*General Manager*

Milano, 30-03-2020

REV.3

ITALCERT

CERTIFICATO N° 505SGQ04

CERTIFICATE N° 505SGQ04

Si certifica che il
this is to certify that

Sistema di Gestione per la Qualità

Quality Management System

messo in atto da
implemented by

APTACA S.p.A.

Via Monte Bianco, 4 – IT 20900 MONZA (MB)

nella Sede Operativa di
Operative Unit

Regione Monforte, 30 – IT 14053 CANELLI (AT)

è conforme alla norma
is in compliance with the standard

UNI EN ISO 9001-2015 (ISO 9001-2015)

per i seguenti Processi
concerning the following kinds of Processes

Gestione della fabbricazione ed immissione in commercio di tamponi sterili per il prelievo di campioni biologici in orifizi naturali e in ambito chirurgico. Progettazione e fabbricazione di dispositivi medico diagnostici per laboratori di analisi. Commercializzazione di dispositivi medici e diagnostici in vitro. Commercializzazione di articoli da laboratorio

Management of the manufacturing and placing on the market of sterile tampons for sampling of biological specimens in natural orifice and in surgical field. Design and manufacturing of diagnostic medical devices for laboratories of analysis. Marketing of medical and diagnostic devices in vitro. Marketing of laboratory articles.

Il presente Certificato è soggetto al rispetto delle condizioni stabilite dai Regolamenti per la certificazione in vigore applicabili.
This Certificate shall satisfy the requirements established in the Rules for the certification in force applicable.
In caso di discordanza tra le lingue utilizzate nella traduzione del contenuto del presente certificato, fare riferimento alla lingua italiana
In cases of discrepancy between the languages used in the translation of the content of this certificate, please refer to the Italian language

L'AMMINISTRATORE DELEGATO
MANAGING DIRECTOR

Dr. Ing. Roberto Cusolito

Data di Prima Emissione *First Issue Date*	Data di Prima Emissione ITALCERT *First Issue Date ITALCERT*	Data di Modifica *Modified Date*	Data di Scadenza *Expiration Date*
1998-07-23	2011-10-30	2019-11-06	2020-10-29

Settore IAF 14 - 29

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 023A
Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

ITALCERT S.r.l. | Viale Sarca, 336 – 20126 Milano (MI) | tel. +39 0266104876 | fax. +39 0266101479 | www.italcert.it | italcertsrl@legalmail.it

ITALCERT

CERTIFICATO N° 505DM06

CERTIFICATE N° 505DM06

Si certifica che il
this is to certify that

Sistema di Gestione per la Qualità

Quality Management System

messo in atto da
implemented by

APTACA S.p.A.

Via Monte Bianco, 4 – IT 20900 MONZA (MB)

nella Sede Operativa di
Operative Unit

Regione Monforte, 30 – IT 14053 CANELLI (AT)

è conforme alla norma
is in compliance with the standard

UNI CEI EN ISO 13485-2016 (ISO 13485-2016)

per i seguenti Processi
concerning the following kinds of Processes

Gestione della fabbricazione e immissione in commercio di tamponi sterili per il prelievo di campioni biologici in orifizi naturali e in ambito chirurgico.
Progettazione e fabbricazione di dispositivi medico diagnostici per laboratori di analisi.
Commercializzazione di dispositivi medici e diagnostici in vitro.

Management of manufacturing and placing on the market of sterile tampons for sampling of biological specimens in natural orifice and in surgical field. Design and manufacturing of diagnostic medical devices for analysis laboratories. Marketing of medical and diagnostic devices in vitro.

Il presente Certificato è soggetto al rispetto delle condizioni stabilite dai Regolamenti per la certificazione in vigore applicabili.
This Certificate shall satisfy the requirements established in the Rules for the certification in force applicable.
In caso di discordanza tra le lingue utilizzate nella traduzione del contenuto del presente certificato, fare riferimento alla lingua italiana
In cases of discrepancy between the languages used in the translation of the content of this certificate, please refer to the Italian language

L'AMMINISTRATORE DELEGATO
MANAGING DIRECTOR

Dr. Ing. Roberto Cusolito

Data di Prima Emissione *First Issue Date*	Data di Prima Emissione ITALCERT *First Issue Date ITALCERT*	Data di Modifica *Modified Date*	Data di Scadenza *Expiration Date*
2007-10-30	2011-10-30	2019-11-06	2020-10-29

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 023A
Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

ITALCERT S.r.l. | Viale Sarca, 336 – 20126 Milano (MI) | tel. +39 0266104876 | fax. +39 0266101479 | www.italcert.it | italcertsrl@legalmail.it

EC-Declaration of Conformity

According to Directive 98/79/EC on in-vitro-diagnostic devices, Annex III

Manufacturer: nal von minden GmbH, Carl-Zeiss Str.12, 47445 Moers
Classification: Other Products

We herewith declare on our sole responsibility that all batches of below mentioned In-vitro-diagnostic devices are conform with the Essential Requirements Annex I of the directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices. The products are suitable for the intended application (only professional users).

Relevant standards and guidelines are applied.

141000	NADAL® EARLY hCG Pregnancy dipstick
141000_SSL	NADAL® EARLY hCG Pregnancy dipstick
141002	NADAL® hCG Pregnancy Test 25 mIU/ml dipstick
142000	NADAL® EARLY hCG 10 mIU/ml cassette
142002	NADAL® hCG Pregnancy Cassette Test 25 mIU/ml
143003	NADAL® hCG Pregnancy Tests 10 mIU/ml dipstick
143004	NADAL® hCG t 25 mIU/ml dipstick
143004_SSL	NADAL® hCG t 25 mIU/ml dipstick
144001N-10	NADAL® hCG Pregnancy Test, Midstream 20 mIU/ml cassette
151002	NADAL® hCG Pregnancy
151002SE	NADAL® hCG Pregnancy rapid test
151003	NADAL® hCG Test 10mIU/ml Urin/Serum Dipstick
152000	NADAL® hCG Pregnancy 10 mIU/ml cassette
152002	NADAL® hCG Pregnancy 25 mIU/ml cassette
152003	NADAL® hCG Pregnancy Test 20 mIU/ml cassette S/P/W

153002	NADAL® hCG Pregnancy TEST 10 mIU/ml Urin/Serum
153003	NADAL® hCG 25 mIU/mln Dipstick
153003_SSL	NADAL® hCG 25 mIU/mln Dipstick
161001	NADAL® hLH Ovulation rapid test
161001_SSL	NADAL® hLH Ovulation rapid test
162001	NADAL® hLH Ovulation rapid test
162001_SSL	NADAL® hLH Ovulation rapid test
164001	NADAL® hLH Ovulation 30 mIU/ml Midstream
165001	NADAL® hLH Ovulation 30 mIU/ml dipstick
165001_SSL	NADAL® hLH Ovulation 30 mIU/ml dipstick
165002	NADAL® hLH Ovulation rapid tests (2,5mm)
165003	NADAL® hLH Ovulation rapid test
165003_SSL	NADAL® hLH Ovulation rapid test
166001	NADAL® hLH Ovulation 30 mIU/ml cassette
172001	NADAL® FSH cassette
172001_SSL	NADAL® FSH cassette
172003N-10	NADAL® FSH cassette
194002	NADAL® pH-Test

201001	NADAL® Syphilis dipstick
201001_SSL	NADAL® Syphilis dipstick
202001	NADAL® Syphilis cassette
202001_SSL	NADAL® Syphilis cassette
203001	NADAL® Syphilis rapid tests
203002	NADAL® Syphilis rapid tests
203002_SSL	NADAL® Syphilis rapid tests
221001A	NADAL® Strep A dipstick
221005	NADAL® Strep A reagent 1
221006	NADAL® Strep A reagent 2
221050N-50	NADAL® Strep A plus rapid tests
222001A	NADAL® Strep A cassette
222007	NADAL® Strep A plus cassette
222008	NADAL® Strep A plus cassette
222011	NADAL® Strep A plus cassette
222049BUL	NADAL® Strep A Scan cassette
222049BUL-20	NADAL® Strep A Scan cassette
232001	NADAL® Strep B cassette
232001_SSL	NADAL® Strep B cassette
232005	NADAL® Strep B reagent 1
232006	NADAL® Strep B reagent 2
241005N-10	NADAL® Influenza A+B dipstick
241006N-25	NADAL® Influenza A+B dipstick
242001	NADAL® Influenza A+B cassette
242006N-10	NADAL® Influenza A/B cassette
252001	NADAL® Mononucleosis cassette
252002	NADAL® Mononucleosis dipstick
252003	NADAL® Mononucleosis cassette
252003N-20	NADAL® Mononucleosis cassette
252005	NADAL® Mononucleosis positive conrtol
252006	NADAL® Mononucleosis negative conrtol
252017N-05	NADAL® Mononucleosis cassette
262001	NADAL® H.Pylori Antikörper cassette
262001_SSL	NADAL® H.Pylori Antikörper cassette
262002	NADAL® H.Pylori Antigen cassette
262003	NADAL® H. pylori Ab cassette
262004BUL	NADAL® H. pylori Scan Ab cassette
262004BUL N-10	NADAL® H. pylori Scan Ab cassette
272001	NADAL® FOB cassette
272001_SSL	NADAL® FOB cassette
272008	NADAL® FOB cassette
272009	NADAL® Hb/Hp Complex cassette
272010	NADAL® FOB cassette
272011	NADAL® Hb/Hp cassette
272011N-25	NADAL® Hb/Hp cassette
272015	NADAL® Hb/Hp Complex cassette
272015_SSL	NADAL® Hb/Hp Complex cassette
272016	NADAL® FOB plus cassette
272031RU	NADAL® Hb/Hp Complex cassette
272031RU-01	NADAL® Hb/Hp Complex cassette
272031RU_SSL	NADAL® Hb/Hp Complex cassette
272035	NADAL® FOB60 plus cassette
272035_SSL	NADAL® FOB60 plus cassette
272037	NADAL® FOB & Hb/Hp patient set
272040	NADAL® FOB II Cassettes
272041	NADAL® FOB60 Cassette
272041_SSL	NADAL® FOB60 Cassette
272042	NADAL® FOB75 Cassette
272043	NADAL® FOB75 II Cassette
282000	NADAL® Troponin I cassette
282001	NADAL® Troponin I cassette
282001_SSL	NADAL® Troponin I cassette
282003	NADAL® Trop I, CK-MB, Myoglobin Combi- cassette
282015	NADAL® Troponin I cassette
292001	NADAL® Myoglobin cassette
292001N-05	NADAL® Myoglobin cassette

302001	NADAL® CK-MB cassette
302001_SSL	NADAL® CK-MB cassette
311003	NADAL® CrP Dipstick
311004	NADAL® CRP plus Dipstick
311006	NADAL® CRP plus Dipstick
312001	NADAL® CrP cassette
312002	NADAL® high sensitive CrP cassette
312017	NADAL® CRP Quant RFID chip
312021BUL	NADAL® CRP Quant cassette
312021NBUL-20	NADAL® CRP Quant cassette
322003N-30	NADAL® Tuberkulose IgG/IgM cassette
322003N-30_SSL	NADAL® Tuberkulose IgG/IgM cassette
331001	NADAL® Mikroalbumin Dipstick
331004N-50	NADAL® Mikroalbumin Dipstick
333001	NADAL® Mikroalbumin Dipstick
351006	NADAL® D-Dimer cassette
351006_SSL	NADAL® D-Dimer cassette
351007	NADAL® D-Dimer cassette
374018	qLabs aPTT-INR Control
431001N-03	NADAL® PROM Test Dipstick
431001N-03_SSL	NADAL® PROM Test Dipstick
431001N-10	NADAL® PROM Test Dipstick
431001N-10_SSL	NADAL® PROM Test Dipstick
431001N-20	NADAL® PROM Test Dipstick
431006N-03	NADAL® PROM Amniotic fluid Dipstick
431006N-10	NADAL® PROM Amniotic fluid Dipstick
431006N-20	NADAL® PROM Amniotic fluid Dipstick
472001N-25	NADAL® Malaria Pf Ag test cassette
472001N-25_SSL	NADAL® Malaria Pf Ag test cassette
472003N-25	NADAL® Malaria 4 species cassette

472003N-10	NADAL® Malaria 4 species cassette
472003_SSL	NADAL® Malaria 4 species cassette
472008	NADAL® Malaria 4 species cassette
472009	NADAL® Maiaria Pf/Pv Ab cassette
472030N-25	NADAL® Malaria Pf/Pan Ag 4Species cassette
472030N-10	NADAL® Malaria Pf/Pan Ag 4Species cassette
472036N-25	NADAL® Malaria Pf/Pan Ag 4Species cassette
481002	NADAL® Adenovirus rapid tests
481003	NADAL® Adenovirus rapid tests
481004	NADAL® Rotavirus rapid tests
481005	NADAL® Rotavirus rapid tests
481006	NADAL® Adenovirus 40/41 strips
481007	NADAL® Adenovirus 40/41 strips
481008	NADAL® Adenovirus Respiratory rapid tests
481013	Adenovirus Positive Control
481015	NADAL® Rota-Adenovirus cassette
481015_SSL	NADAL® Rota-Adenovirus cassette
481015N-20	NADAL® Rota-Adenovirus cassette
481016	NADAL® Adenovirus cassette
481016_SSL	NADAL® Adenovirus cassette
481017	NADAL® Rotavirus cassette
481049BUL	NADAL® Rota-Adenovirus Scan cassette
481049BUL-10	NADAL® Rota-Adenovirus Scan cassette
491000N-10	NADAL® RSV plus Dipstick
491000N-10_SSL	NADAL® RSV plus Dipstick
491003N-25	NADAL® RSV Dipstick
491005	NADAL® RSV cassette
491008BUL	NADAL® RSV Scan cassette
491009	NADAL® RSV-Adeno Resp cassette
491015	NADAL® RSV Dipstick
495001	NADAL® MRSA Screen Latex-Agglutinationstest

495001_SSL	NADAL® MRSA Screen Latex-Agglutinationstest
501006	NADAL® *E.coli* O157 Cassette
501006_SSL	NADAL® *E.coli* O157 Cassette
501012	NADAL® EHEC Verotoxin 1-2, feces - cassette á 10
501012_SSL	NADAL® EHEC Verotoxin 1-2, feces - cassette á 10
511002	NADAL® Cryptosporidium Dipstick
511006	NADAL® Cryptosporidium cassette
511006_SSL	NADAL® Cryptosporidium cassette
521001	NADAL® Giardia Dipstick
521004	NADAL® Crypto/Giardia Test strips
521006	NADAL® Giardia cassette
521009	NADAL® Giardia cassette
521010	NADAL® Giardia-Crypto-Combo cassette
521010_SSL	NADAL® Giardia-Crypto-Combo cassette
532001_SSL	NADAL® Dengue cassette
532001N-25	NADAL® Dengue cassette
532002N-25	NADAL® Dengue cassette
532003N-25	NADAL® Dengue cassette
532004N-25	NADAL® Dengue cassette
532004N-25_SSL	NADAL® Dengue cassette
532011	NADAL® Dengue IgG/IgM cassette
532011N-25	NADAL® Dengue IgG/IgM cassette
532012N-25	NADAL® Dengue NS1 Ag Cassette
532016N-25	NADAL® Dengue NS1 Ag+IgG/IgM Cassette
542001N-25	NADAL® Tetanus cassette
552005	NADAL® Legionella Urin Antigen cassette
552005_SSL	NADAL® Legionella Urin Antigen cassette
552006	NADAL® Legionella Urin Antigen cassette
552006_SSL	NADAL® Legionella Urin Antigen cassette

552020	NADAL® Legionella Urine Antigen test
562003N-10	NADAL® BCA/HB inkl.
562003RU	NADAL® BCA/HB inkl.
572004N-10	NADAL® Streptococcus pneumoniae cassette
572005	NADAL® Legionella/S. pneumonia cassette
580005N-25	NADAL® TSH cassette
582003	NADAL® C. difficile Toxin A/B cassette
582003_SSL	NADAL® C. difficile Toxin A/B cassette
582004	NADAL® Clostridium Difficile GDH
582008	NADAL® Clostridium Difficile Toxins A&B cassette
582009	NADAL® C. perfringens Ag cassette
582009_SSL	NADAL® C. perfringens Ag cassette
582016N-10	NADAL® Clostridium Difficile Toxin A+B/GDH Cassette
600002N-30	NADAL® Rheumatoid Factor test cassette
611003N-10	NADAL® Gonorrhea cassette
611003N-10_SSL	NADAL® Gonorrhea cassette
611005N-10	NADAL® Gonorrhea cassette
612004N-25	NADAL® CCA (Bilharzia) cassette
622001N-30	NADAL® HAV IgM test cassette
622040N-30	NADAL® HEV IgM cassette
622070N-30	NADAL® HAV IgG/IgM cassette
622070N-30_SSL	NADAL® HAV IgG/IgM cassette
652001N-30	NADAL® Chagas IgG cassette
652001N-30_SSL	NADAL® Chagas IgG cassette
662001N-30	NADAL® Leishmania cassette
672001N-30	NADAL® Filariasis cassette
672001N-30_SSL	NADAL® Filariasis cassette
682002N-20	NADAL® Chikungunya IgM Cassette

692001N-30	NADAL® Typhus Cassette
692001N-30_SSL	NADAL® Typhus Cassette
712001	NADAL® AFP Cassette
712001_SSL	NADAL® AFP Cassette
722003	NADAL® CEA Cassette
722003_SSL	NADAL® CEA Cassette
790001	NADAL® Celiac Disease tTG Cassette
790001_SSL	NADAL® Celiac Disease tTG Cassette
790002	NADAL® Celiac Disease tTG & Gliadine Cassette
795002	NADAL® ASO Latex
795003	NADAL® ASO Latex
795005	NADAL® CRP Latex
795006	NADAL® CRP Latex
795008	NADAL® RF Latex
795008_SSL	NADAL® RF Latex
795009	NADAL® RF Latex
795010	NADAL® RPR Carbon Latex
795011	NADAL® RPR Latex
795015	NADAL® VDRL
795016	NADAL® VDRL
795017	NADAL® Waaler Rose Latex
795018	NADAL® Waaler Rose Latex
795024	NADAL® IM Latex
795027	NADAL® TPHA
795028	NADAL® TPHA
795030	NADAL® Rose Bengale
850003	NADAL®Astrovirus Test Cassette
850003N-10	NADAL®Astrovirus Test Cassette
860001	NADAL® Bence Jones Proteinurie Dipstick
870001	NADAL® Lyme Borreliose Cassette
920001	NADAL® Norovirus Cassette
920001_SSL	NADAL® Norovirus Cassette
920002	NADAL® Norovirus I+ II Cassette
920002_SSL	NADAL® Norovirus I+ II Cassette
1010002N-20	NADAL® Cholera O1/O139 cassette
1120003N-20	NADAL®Candida Albicans (Cassette á 20)
1130002N-30	NADAL® HSV-1 IgG/IgM - Herpes-Simplex-Virus
1130003N-30	NADAL®HSV-2 IgG/IgM - Herpes-Simplex-Virus
1200001	NADAL® Lactoferrin Test Feces (Cassette á 10)
1201004N-10	NADAL® Ferritin cassette
1212001	NADAL® Calprotectin Test Feces (TK á 10)
1212001_SSL	NADAL® Calprotectin Test Feces (TK á 10)
1212002	NADAL® Calprotectin +Lactoferrin Test Feces (TK á 10)
1222001	NADAL® Enterovirus Test Feces (TK á 10)
1222001_SSL	NADAL® Enterovirus Test Feces (TK á 10)
1232001	NADAL® Campylobacter Test Feces (TK á 10)
1242001	NADAL® Salmonella spp. Test Feces (TK á 10)
1242002	NADAL® Salmonella Typhi-Test Feces (TK á 10)
1252001	NADAL® Listeria-Test Feces (TK á 10)
1262001	NADAL® Shigella-Test - Feces (TK à 10)
1262002	NADAL® Shigella Dysenteriae-Test Feces (TK à 10)
1320002	NADAL® HB Hämoglobin Dipstick (á 50)

1320003	NADAL® HB Kontroll Dipstick (á 2)
1320004	NADAL® HB Kapillarröhrchen 10 µl (á 50)
2090001	NADAL® Entamoeba cassette
2090001_SSL	NADAL® Entamoeba cassette
2200001	NADAL® IgG cassette
2201001N-10	NADAL® IgE cassette
2210001	NADAL® IgE cassette
2210001_SSL	NADAL® IgE cassette

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