Glocal Linker, Healthcare Better; Dream Maker, Win Together >>>

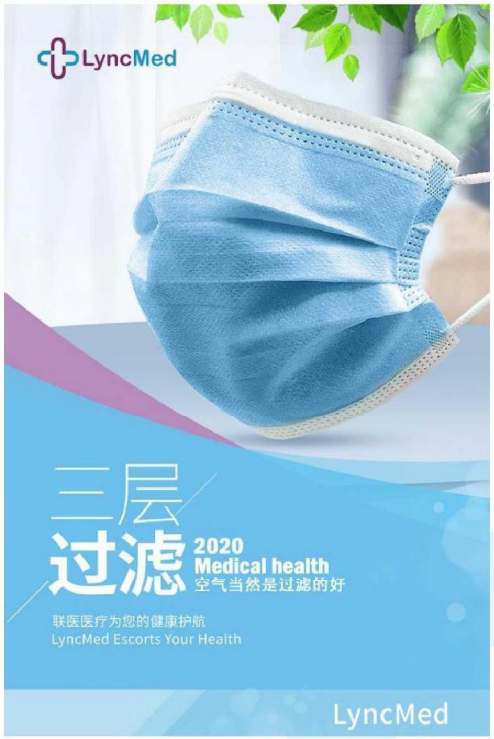
LyncMed

Disposable Face Mask
Product Profile

KA International Business Dept

Lyncmed Medical Group

Lyncmed Product Profile



3 Layer Non-woven Disposable Face Mask

Disposable Face Mask Key Features:

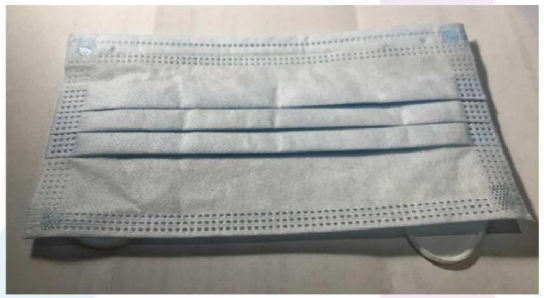
-Skin Friendly High Quality PP Material, 3-Ply

-Low Breathing Resistance, Bacterial Filtration Efficiency(BEF)>98%

-Ear Loop, Elastic Band, Latex Free

-Anatomic Adjustable Integrated nose bridge

-Size:17.5*9.5cm



Face Mask Packing Info

Packing Size: 52*38*30cm
Net Weight: 6.0KG
Gross Weight: 6.5KG
Quantity: 2000pcs/carton
(40box/carton,50pcs/box)

Face Mask Certificates –EN14683 BEF Test Report

Nelson Labs
A Sotera Health company

Sponsor:
5.1.2e
Lyncmed Medical Technical (Beijing) Co., Ltd
Room 119, No. 1111
South Huihe Road, Chaoyang District
Beijing, 100000
CHINA

Bacterial Filtration Efficiency (BFE) and Differential Pressure (Delta P) Final Report

Test Article: Product Name: Non-woven Face mask
LOT No.: CMA4714
Study Number: 1088913-S01
Study Received Date: 23 Aug 2018
Testing Facility: Nelson Laboratories, LLC
6280 S. Redwood Rd.
Salt Lake City, UT 84123 U.S.A.
Test Procedure(s): Standard Test Protocol (STP) Number: STP0004 Rev 15
Deviation(s): None

Summary: The BFE test is performed to determine the filtration efficiency of test articles by comparing the bacterial control counts upstream of the test article to the bacterial counts downstream. A suspension of *Staphylococcus aureus* was aerosolized using a nebulizer and delivered to the test article at a constant flow rate and fixed air pressure. The challenge delivery was maintained at 1.7 - 2.7 x 10^3 colony forming units (CFU) with a mean particle size (MPS) of 3.0 ± 0.3 µm. The aerosols were drawn through a six-stage, viable particle, Andersen sampler for collection. This test method complies with ASTM F2101-14, EN 14683:2014, Annex B, and AS4381:2015.

The Delta P test is performed to determine the breathability of test articles by measuring the differential air pressure on either side of the test article using a manometer, at a constant flow rate. The Delta P test was designed to comply with MIL-M-36954C, Section 4.4.1.2 and complies with EN 14683:2014, Annex C and AS4381:2015.

All test method acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Test Side: Inside
BFE Test Area: ~40 cm^2
BFE Flow Rate: 28.3 Liters per minute (L/min)
Delta P Flow Rate: 8 L/min
Conditioning Parameters: 85 ± 5% relative humidity (RH) and 21 ± 5°C for a minimum of 4 hours
Test Article Dimensions: ~177 mm x ~158 mm
Positive Control Average: 2.5 x 10^3 CFU
Negative Monitor Count: <1 CFU
MPS: 3.1 µm

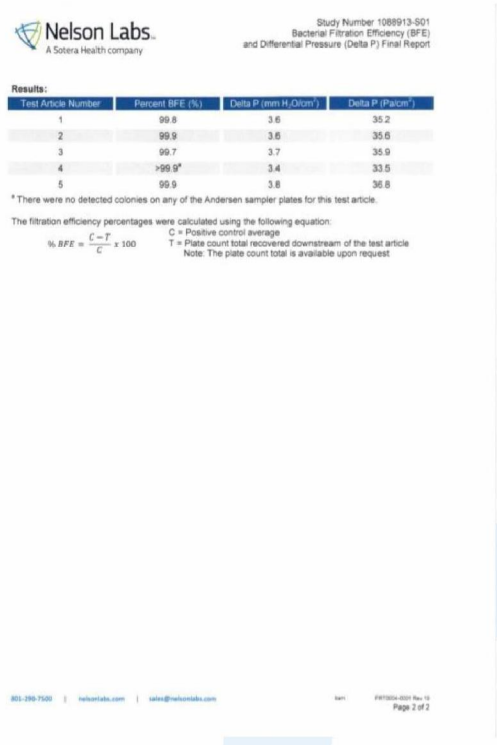
5.1.2e

10 Sep 2018
Study Completion Date

1088913-S01

801-290-7500 | nelsonlabs.com | sales@nelsonlabs.com

Page 1 of 2



Nelson Labs
A Sotera Health company

Study Number 1088913-S01
Bacterial Filtration Efficiency (BFE)
and Differential Pressure (Delta P) Final Report

Results:

Test Article Number	Percent BFE (%)	Delta P (mm H_2O/cm^2)	Delta P (Pa/cm^2)
1	99.8	3.6	35.2
2	99.9	3.6	35.6
3	99.7	3.7	35.9
4	>99.9*	3.4	33.5
5	99.9	3.8	36.8

* There were no detected colonies on any of the Andersen sampler plates for this test article.

The filtration efficiency percentages were calculated using the following equation:

$$\% BFE = \frac{C-T}{C} \times 100$$

C = Positive control average
T = Plate count total recovered downstream of the test article
Note: The plate count total is available upon request

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Page 2 of 2

Face Mask Certificates –EN14683 MC Test Report

Nelson Labs.
A Sotera Health company

Sponsor:
Mavis CUI
Lyncmed Medical Technical (Beijing) Co.
Room 119, No. 1111, South Huihe Rd., Chaoyang District
Beijing, 100000
CHINA

Microbial Cleanliness (Bioburden) of Medical Masks Final Report

Test Article: Product Name: Non-woven Face mask
LOT #CMA4714
Study Number: 1088914-S01
Study Received Date: 23 Aug 2018
Testing Facility: Nelson Laboratories, LLC
6280 S. Redwood Rd.
Salt Lake City, UT 84123 U.S.A.
Test Procedure(s): Standard Test Protocol (STP) Number: STP0036 Rev 14
Customer Specification Sheet (CSS) Number: 201805306 Rev 01
Deviation(s): None

Summary: The testing was conducted in accordance with EN 14683:2014, with the exception of approximate volumes of eluent used when performing the extraction procedure and a temperature range of 30-35°C used for aerobic incubation.

When bioburden results are calculated using a software program, manual calculations may differ slightly due to rounding. The counts determined on products are colony forming units and may not always reflect individual microorganisms. The sponsor performs any statistical analysis and determines the acceptable limits. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Results:

Unit Number	Weight (g)	Aerobic	Fungal	Total Bioburden (CFU/mask)	Total Bioburden (CFU/g)
1	3.2	88	12[a]	99.7	31.1
2	3.3	49	3[a]	51.9	15.7
3	3.3	33	3[a]	35.9	10.9
4	3.4	51	<3	54.2	15.9
5	3.4	68	9[a]	77.5	22.8
Recovery Efficiency			65.7%		

< = No Organisms Detected
Note: The results are reported as colony forming units (CFU) per mask.
Note: Sample positive testing was performed using *Bacillus atrophaeus*. The test article was not inhibitory using this test method.
[a] Spreader. Count is considered a minimum estimate due to swarming of certain colonies on the membrane.

5.1.2e

IAC-MRA ANAB

14SEP2018
Study Completion Date

1088914-S01

Test Method Acceptance Criteria: If applicable, anaerobic controls are acceptable for the bioburden test results. The number of masks to be tested shall be a minimum of 5 or more to meet an acceptable quality level of 4%. The bioburden of the medical mask shall be < 30 cfu/g tested.

Procedure:
Positive Controls/Monitors: *Bacillus atrophaeus*
Extract Fluid: Peptone Tween® with Sodium Chloride
Extract Fluid Volume: ~300 mL
Extract Method: Orbital Shaking for 5 minutes at 250 rpm
Plating Method: Membrane Filtration
Agar Medium: Tryptic Soy Agar
Sabouraud Dextrose Agar with Chloramphenicol
Recovery Efficiency: Exhaustive Rinse Method
Aerobic Bacteria: Plates were incubated 3 days at 30-35°C, then enumerated.
Fungal: Plates were incubated 7 days at 20-25°C, then enumerated.

Face Mask Certificates –EN14683 SBPR & EN14683 Blood Penetration Resistance Report

Nelson Labs
A Sotera Health company

Sponsor: 5.1.2e
Lynemed Medical Technical (Beijing) Co., Ltd
Room 119, No. 1111,
South Huihe Road, Chaoyang District
Beijing, 100000
CHINA

Synthetic Blood Penetration Resistance Final Report

Test Article: Product Name: Non-woven Face mask
LOT #CMA4714
Study Number: 1088912-S01
Study Received Date: 23 Aug 2018
Testing Facility: Nelson Laboratories, LLC
6280 S. Redwood Rd.
Salt Lake City, UT 84123 U.S.A.
Test Procedure(s): Standard Test Protocol (STP) Number: STP0012 Rev 08
Deviation(s): None

Summary: This procedure was performed to evaluate surgical facemasks and other types of protective clothing materials designed to protect against fluid penetration. The purpose of this procedure is to simulate an arterial spray and evaluate the effectiveness of the test article in protecting the user from possible exposure to blood and other body fluids. The distance from the target area surface to the tip of the cannula is 30.5 cm. A test volume of 2 mL of synthetic blood was employed using the targeting plate method.

This test method was designed to comply with ASTM F1862 and ISO 22609 (as referenced in EN 14683:2014 and AS4381:2015) with the following exception: ISO 22609 requires testing to be performed in an environment with a temperature of 21 ± 5°C and a relative humidity of 85 ± 10%. Instead, testing was performed at ambient conditions within one minute of removal from the environmental chamber held at those parameters.

All test method acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Number of Test Articles Tested: 32
Number of Test Articles Passed: 30
Test Side: Outside
Pre-Conditioning: Minimum of 4 hours at 21 ± 5°C and 85 ± 5% relative humidity (RH)
Test Conditions: 18.8°C and 32% RH

Results: Per ASTM F1862 and ISO 22609, an acceptable quality limit of 4.0% is met for a normal single sampling plan when ≥29 of 32 test articles show passing results.

Test Pressure: 120 mmHg (16.0 kPa)

Test Article Number	Synthetic Blood Penetration
1-18, 20-26, 28-32	None Seen
19, 27	Yes

5.1.2e

10 Sep 2018
Study Completion Date

1088912-S01

801-290-7500 | nelsonlabs.com | sales@nelsonlabs.com

FR10012-0002 Rev 10
Page 1 of 1

NELSON LABORATORIES

Sponsor: 5.1.2e
LyncMed Group
No. 1111, South HuiHe Road,
100025, Beijing CHINA

EN 14683:2005 Synthetic Blood
Penetration Resistance Final Report

Test Article: Non-woven Facemask
Laboratory Number: 735314
Study Received Date: 27 Jan 2018
Test Procedure(s): Standard Test Protocol (STP) Number STP0012 Rev.05

Summary: This procedure was performed to evaluate surgical facemasks and other types of protective clothing materials designed to protect against fluid penetration. The purpose of this procedure is to simulate an arterial spray and evaluate the effectiveness of the material in protecting the user from possible exposure to blood and other body fluids. The distance from the target area surface to the tip of the cannula is 30.5 cm. A test volume of 2 mL of synthetic blood was employed. This test method was designed to comply with ASTM F1862 and EN 14683:2005. All test method acceptance criteria were met.

Number of Test Articles Tested: 32
Number of Test Articles Passed: 32
Test Side: Outside
Pre-Conditioning: Minimum of 4 hours at 21 ± 5°C and 85 ± 5% relative humidity (RH)
Test Conditions: 22.5°C and 21% RH

5.1.2e

07 Feb 2019
Study Completion Date

FR10012-0001 Rev 6
Page 1 of 2

Face Mask CE Certificate

Lyncmed Medical Technology(Beijing) Co., Ltd.

EC DECLARATION OF CONFORMITY

Manufacturer: Lyncmed Medical Technology(Beijing) Co., Ltd.
Room 119, No.1111 South Huihe Rd, Chaoyang District 100022 Beijing, China

whose single Authorized Representative: SUNGO Certification Company Limited
RM101, MAPLE HOUSE, 118 HIGH STREET, PURLEY, LONDON, ENGLAND

We declare under our sole responsibility that :

the medical device: -Non-woven products:Surgical gowns, Surgical drapes, Surgical packs, Pouches,Caps,Coveralls,Facemasks,Suits,Underpad,Gloves, Towels,Wipes, Sheets, Packs, Shoe covers, Aprons, Gowns, Trousers,Sleeve covers, Pillow covers, Beard covers, Bags,Bibs, Rolls,Briefs, Hair bands;
-Disposable PE products:Shoe covers, Tray covers, Pouches, Caps, Gloves, Aprons, Gowns, Sleeve covers, Bags, Sheets, Pillow case, Pallet covers, Bibs;
-Disposable Vinyl examination gloves
-Disposable Nitrile examination gloves
-Disposable Latex examination gloves
-Urine Cup for single use
-Urine Bag for single use

(Name, type or model, batch or serial number, possibly sources and number of items)

of class: Class I

according to annex IX of direct. 93/42/EEC

meets all the provisions of the directive 93/42/EEC (or 90/385/EEC) which apply to it.

Conformity assessment procedure: 93/42/EEC, Annex V

The above mentioned declaration of conformity is exclusively under the responsibility of: Lyncmed Medical Technology(Beijing) Co., Ltd.

Place , date: Beijing 20th Dec. 2017

5.1.2e Management Representative

Legally binding signature / function

5.1.2e

EC Declaration of Conformity

CE Certificate

Technical Data Sheet

TECHNICAL DATA SHEET - CONFIDENTIAL

This information shall not be disclosed to any other party

Product	Medical Face Masks, 3 ply	
Quality	Norm EN 14683, Type I	
	BFE %	≥ 95
	Differential Pressure (Pa/cm²)	≤ 29,4
	Splash Resistance Pressure (mm Hg)	not required
	CfU/g	< 30
Lab test	lab test must be provided, showing that the lot meets the EN 14683 Type I requirements	
Material	Latex free, 3 ply mask: 1st ply, outside 25 gsm non-woven 2nd ply, 25 gsm melt blown filter 3rd ply, inside 25 gsm nonwoven	
Size & fixture	earloop: body 17,5 x 9.5 cm, ultrasonically welded latex free earloops at the outside of mask body	
Packaging		
primary	50 pcs per box with lot numer and color marked on the square on the box	
secondary	earloop case 40x50 pcs case white with full color label, size 52x38x30 cm	
Intended Use	The intended use of a medical face mask is to help prevent large particles expelled by the wearer (e.g. spit, mucous) from reaching the patient or work environment. Fluids contacting the outer surface of the surgical mask will not immediately soak through to the interior of the surgical mask and contact the wearer's lips or skin.	
Wear	Medical face masks are typically donned for a specific procedure. For infection control purposes masks are typically disposed of after each procedure/patient activity.	
Fit	Medical face masks are not designed to pass a fit test. Flat surgical masks fit loosely over the face leaving large gaps between the mask and the wearer. It is unlikely that most of the air will pass through the mask material. The air (and any airborne particles) will go through the gaps	
Shelf life	5 years after production date	
Lot	to be traced back by the factory in case of recall or QA issues	
QA documents	MDD 93/42/EEC Guideline, EN 14683	

Lyncmed Company Certificate

统一社会信用代码
91110108MA002T3N4R

营业执照

(副本)(1-1)

扫描二维码登录"国家企业信用信息公示系统"了解更多登记、备案、许可、监管信息

名　　称　联医医疗科技（北京）有限公司
类　　型　其他有限责任公司
法定代表人　王鹏
经营范围　技术开发、技术推广、技术转让、技术咨询、技术服务；经济贸易咨询；企业管理咨询；销售自行开发的产品；计算机系统服务；应用软件服务；软件开发；软件咨询；电脑动画设计；企业策划；设计、制作、代理、发布广告；组织文化艺术交流活动（不含营业性演出）；销售机械设备、计算机、软件及辅助设备、医疗器械Ⅰ类、Ⅱ类、日用杂货；技术进出口、代理进出口、货物进出口；销售第三类医疗器械。（企业依法自主选择经营项目，开展经营活动；销售第三类医疗器械以及依法须经批准的项目，经相关部门批准后依批准的内容开展经营活动；不得从事本市产业政策禁止和限制类项目的经营活动。）

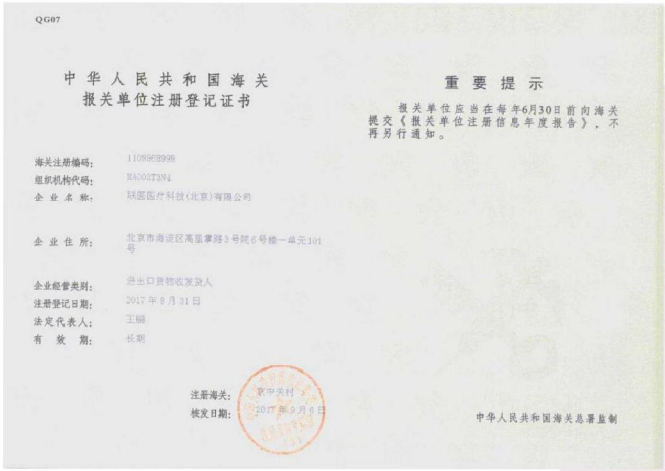
注册资本　225.972万元
成立日期　2015年12月29日
营业期限　2015年12月29日 至 2035年12月28日
住　　所　北京市海淀区高里掌路3号院6号楼一单元101号

登记机关　北京市工商行政管理局海淀分局

2019年 03月 19日

国家企业信用信息公示系统网址：http://www.gsxt.gov.cn　市场主体应当于每年1月1日至6月30日通过国家企业信用信息公示系统报送公示年度报告。　国家市场监督管理总局监制

Business License



QG07

中华人民共和国海关
报关单位注册登记证书

重要提示

报关单位应当在每年6月30日前向海关提交《报关单位注册信息年度报告》，不再另行通知。

海关注册编码：1108963998
组织机构代码：MA002T3N4
企业名称：联医医疗科技(北京)有限公司
企业住所：北京市海淀区高里掌路3号院6号楼一单元101号
企业经营类别：进出口货物收发货人
注册登记日期：2017年8月31日
法定代表人：王鹏
有效期：长期

注册海关：京中关村
核发日期：2017年9月6日

中华人民共和国海关总署监制

Export Customs License

Lyncmed Company Certificate


NO. 0036827423

机构信用代码证

代　码：G1011010816830790 4

名　称：联医医疗科技（北京）有限公司

地　址：北京市海淀区中关村南三街6号中科资源大厦5层52603号

有效期：截至2021年01月13日

2016年 01月 14日

中国人民银行征信中心 制

THE PEOPLE'S BANK OF CHINA CREDIT REFERENCE CENTRE

Our Bank Reputation Certificate


第二类医疗器械经营备案凭证

备案编号：京海食药监械经营备20170384号

企业名称	联医医疗科技（北京）有限公司
法定代表人	王鹏
企业负责人	唐晓科
经营方式	批发
住 所	北京市海淀区高里掌路3号院6号楼一单元101号
经营场所	北京市海淀区高里掌路3号院6号楼一单元101号
库房地址	北京市海淀区高里掌路3号院6号楼一单元101号
经营范围	2002年版分类目录：Ⅱ类：6801、6806、6807、6810、6864、6820、6866、6812、6826、6840（仅限不需冷链储运诊断试剂）、6840（含诊断试剂）、6841、6854、6855、6856、6863、6822、6831、6823、6824、6830、6857、6870、6846、6821*** 2017年版分类目录：Ⅱ类：01,02,03,04,06,07,08,11,14,16,17,18,21,22,6840体外诊断试剂（不需冷链运输、贮存）***

备案部门（备案专用章）

备案日期：2020年06月19日

Medical Equipment Business Registration License

Lyncmed Company Certificate

TÜVRheinland

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Lyncmed Medical Technology
(Beijing) Co., Ltd.
Room 119, Floor 1
GUOTOUSHANGKE Building
No. 1111, South Huihe Road
ChaoYang District
100022 Beijing
China

has established and applies a quality management system for medical devices for the following scope:

Manufacture and Distribution of Medical Devices

(see attachment for products included)

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2018-12-04
Certificate Registration No.: SX 60133386 0001
An audit was performed. Report No.: 50180180 002
This Certificate is valid until: 2021-12-03

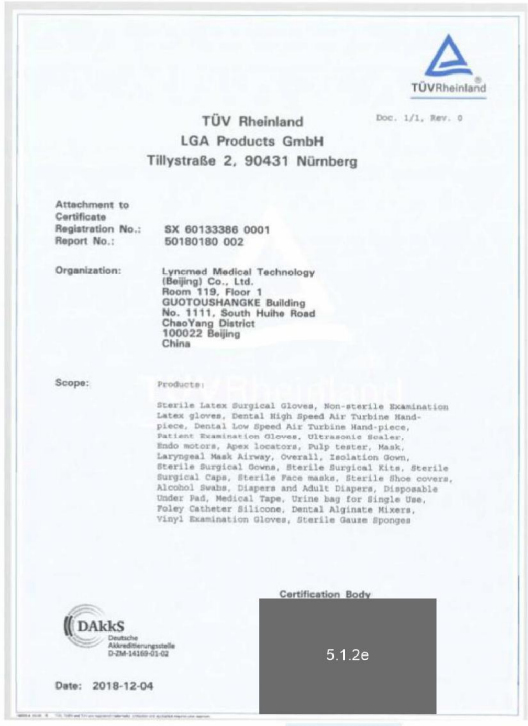
Certification Body

5.1.2e

DAkkS Deutsche Akkreditierungsstelle D-ZM-14169-01-02

Date: 2018-12-04

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg



TÜVRheinland

Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60133386 0001
Report No.: 50180180 002

Organization: Lyncmed Medical Technology
(Beijing) Co., Ltd.
Room 119, Floor 1
GUOTOUSHANGKE Building
No. 1111, South Huihe Road
ChaoYang District
100022 Beijing
China

Scope:

Products:

Sterile Latex Surgical Gloves, Non-sterile Examination Latex gloves, Dental High Speed Air Turbine Hand-piece, Dental Low Speed Air Turbine Hand-piece, Patient Examination Gloves, Ultrasonic Scaler, Endo motors, Apex locators, Pulp tester, Mask, Laryngeal Mask Airway, Overall, Isolation Gown, Sterile Surgical Gowns, Sterile Surgical Kits, Sterile Surgical Caps, Sterile Face masks, Sterile Shoe covers, Alcohol Swabs, Diapers and Adult Diapers, Disposable Under Pad, Medical Tape, Urine bag for Single Use, Foley Catheter Silicone, Dental Alginate Mixers, Vinyl Examination Gloves, Sterile Gauze Sponges

Certification Body

5.1.2e

DAkkS Deutsche Akkreditierungsstelle D-ZM-14169-01-02

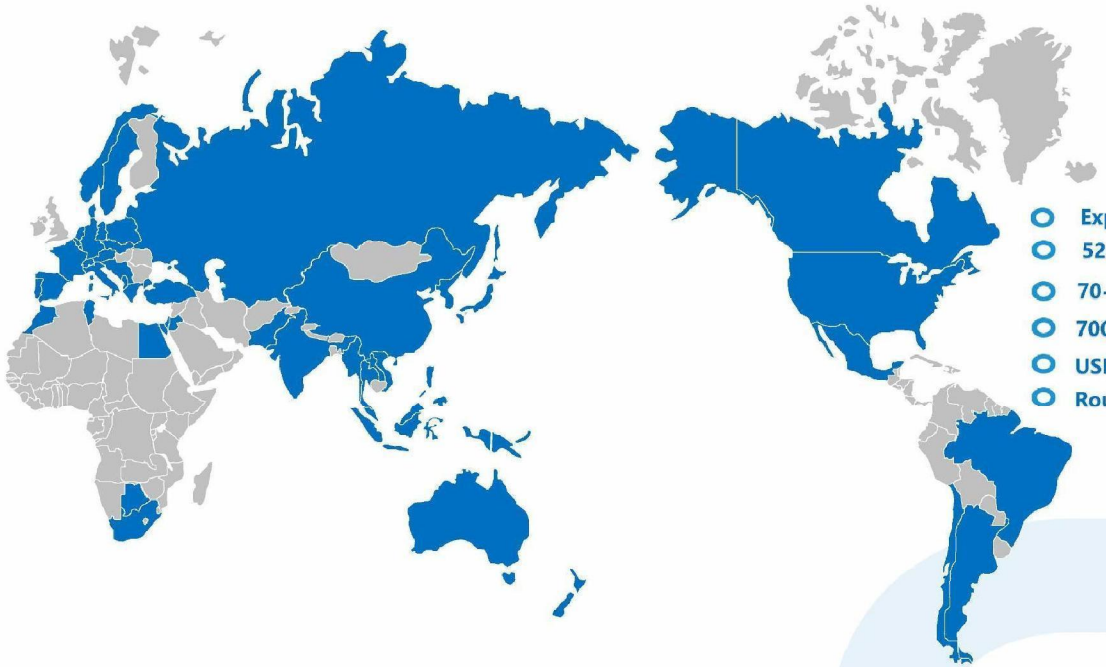
Date: 2018-12-04

ISO-13485 Certificate


INTELINNOVATION
联医英泰

Product Workshop

Our Global Distribution Network



- Exporting to more than 60 countries
- 520 employees worldwide
- 70-100 containers per month
- 700+ customers all over the world
- USD 60 Million in revenue in 2018
- Roughly 70% of production to export

We make better healthcare accessible affordable and easily available

Our Warehouse

LyncMed

Warehouse Inside

Warehouse Outside

Warehouse Truck Loading

Thanks for all

Glocal Linker, Healthcare Better; Dream Maker, Win Together >>>