TÜVRheinland®

EC Certificate

Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

Registration No.: DD 60140740 0001

Report No.: 15070840 008

Manufacturer: V&Q Manufacturing Corporation
4A Fuyuan Road, Pengchang Tow
Xiantao City
433018 Hubei
China

Products: Medical Devices

(see attachm ed)

Replaces No.: DD 60122784 0001

Expiry Date:

The Notified Body h irements of Annex V of the directive 93/42/EEC have been met for the named manufacturer has established and applies a quality assurance syst odic surveillance, defined by Annex V, section 4 of the aforemention the market of class IIb and class III devices covered by this certificate ificate according to Annex III is required.

Eff -07-04

2019-07-04

Notified Body

Fuxiu Sheng

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

NELSON LABORATORIES

Sponsor:
Jacky Jin
V&Q Manufacturing Corporation
#B1614 Optical Valley Times Square
Guanshandadao Hongshan District
Wuhan City, Hubei Province,
CHINA

Flammability of Clothing Textiles Final Report

Test Article: VQN0185W-3
Study Number: 947950-S01
Study Received Date: 22 Feb 2017
Test Procedure(s): Standard Test Protocol (STP) Number: 801-STP0073 Rev 06

Summary: This procedure was performed to evaluate the flammability of plain [illegible] by measuring the ease of ignition and the speed of flame spread. The para[illegible] separate materials into different classes, thereby assisting in a judgment of [illegible] and protective clothing material. The test procedure was performed in ac[illegible] outlined in 16 CFR Part 1610 (a) *Step 1 - testing in the original state* [illegible] *after refurbishing*, was not performed. All test method acceptan[illegible] performed in compliance with US FDA good manufacturing practic[illegible] 211 and 820.

Test Article Side Tested: Outside Surface
Orientation: Machine

Test Criteria for Specimen Classification (See 16 C[illegible]

Class	[illegible]urface Textile Fabric
1	[illegible]rn time ≥3.5 seconds
2	[illegible]cable to plain surface textile fabrics
3	Burn time <3.5 seconds

The 16 CFR Part 1610 standar[illegible]es are to be tested if, during preliminary testing, only 1 test article exhibits fl[illegible]s than 3.5 seconds or the test articles exhibit an average flame spread le[illegible]e replicates are to be tested if no flame spread is observed upon prelimi[illegible]rticle exhibits flame spread and it is equal to or greater than 3.5 seconds, o[illegible]ad is equal to or greater than 3.5 seconds. In accordance with the standard [illegible]r this study.

Results:

[illegible]er	Time of Flame Spread
[illegible]	DNI
[illegible]	DNI
3	DNI
4	DNI
5	DNI

DNI = Test [illegible]ticle did not ignite

Janelle Bentz for
Study Director — Brandon L. Williams

07 Mar 2017
Study Completion Date

947950-S01

NELSON LABORATORIES

Sponsor:
Jacky Jin
V&Q Manufacturing Corporation
#B1614 Optical Valley Times Square
Guanshandadao Hongshan District
Wuhan City, Hubei Province,
CHINA

Synthetic Blood Penetration Resistance Final Report

Test Article: VQN0185W-3
Study Number: 947953-S01
Study Received Date: 22 Feb 2017
Test Procedure(s): Standard Test Protocol (STP) Number: 801-STP0012 Rev 06

Summary: This procedure was performed to evaluate surgical facemasks and clothing materials designed to protect against fluid penetration. The purp simulate an arterial spray and evaluate the effectiveness of the test artic possible exposure to blood and other body fluids. The distance from th the cannula is 30.5 cm. A test volume of 2 mL of synthetic blood was method.

This test method was designed to comply with ASTM F EN 14683:2014) with the following exception. ISO 226 environment with a temperature of 21 ± 5°C and a rela performed at ambient conditions within one minute o those parameters.

All test method acceptance criteria were met manufacturing practice (GMP) regulations 2

Number of Test Articles Tested:
Number of Test Articles Passed:
Test Sid
Pre-Conditio at 21 ± 5°C and 85 ± 5% relative humidity (RH)
Test Con RH

Results: Per ASTM acceptable quality limit of 4.0% is met for a normal single sampling plan wh now passing results.

m Hg

	Synthetic Blood Penetration
	None Seen

Study Director Brandon L. Williams

09 Mar 2017
Study Completion Date

947953-S01

NELSON LABORATORIES

Sponsor:
Jacky Jin
V&Q Manufacturing Corporation
#B1614 Optical Valley Times Square
Guanshandadao Hongshan District
Wuhan City, Hubei Province,
CHINA

Latex Particle Challenge Final Report

Test Article:	VQN0185W-3-1 VQN0185W-3-2 VQN0185W-3-3 VQN0185W-3-4 VQN0185W-3-5
Study Number:	947951-S01
Study Received Date:	22 Feb 2017
Test Procedure(s):	Standard Test Protocol (STP) Number: 801-STP0005

Summary: This procedure was performed to evaluate the non-viable parti) of the test article. Monodispersed polystyrene latex spheres (PSL) wer assed through the test arti g a laser particle counter.

Three one-minute counts were performed, with the test article esults averaged. Three one-minute control counts were performed, without , before and after each test article and the counts were averaged. Control etermine the average number of particles delivered to the test article. The fil ated using the average number of particles penetrating the test article comp ontrol values.

The procedure employed the basic particle f in ASTM F2299, with some exceptions; notably the procedure incorporat nge. In real use, particles carry a charge, thus this challenge represents a m neutralized aerosol is also specified in the FDA guidance document on sur method acceptance criteria were met. Testing was performed in complianc ufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Test S
Area T
Par
Laborator elative humidity (RH) at 0758; 21°C, 23% RH at 1030
Average Filtra
St

Results:

Test	st Article Counts	Average Control Counts	Filtration Efficiency (%)
VQ	35	13,428	99.74
	34	13,140	99.74
	31	13,057	99.76
	31	13,190	99.76
	42	13,286	99.68

Study Director — Brandon L. Williams

ANAB ACCREDITED TESTING LABORATORY

10 Mar 2017
Study Completion Date

947951-S01

TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

V&Q Manufacturing Corporation
4A Fuyuan Road, Pengchang To
Xiantao City
433018 Hubei
China

has established and applies a quality m edical devices
for the fol

Manufacture and D al Devices

(see attac included)

Proof has equirements specified in

13485:2016

are gement system is subject to yearly surveillance.

Effec 2018-02-12

o.: SX 60122785 0001

med. Report No.: 15070840 005

is valid until: 2020-07-24

Certification Body

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

Date 2018-02-12

K. Ren

AAB

PROTECTIVE BREATHING

MASK

Anti-fog/Anti-droplets/Anti-dust

Long-last

Effectiv

Bend

10 pcs

KN95 | ffp2 | EN 149:200

CE

AAB

Method of use

1. Keep you hand dry and unfold the mask.
2. Keep the white side to your face and the nose clip along to the upside.
3. Hang on to your face with the ear loops and adjust the both loops even, then press the nose clip.
4. Adjust the facemask to the most fit of your face in each side.

Notes

- Wash your hands before wearing the mask and avoid any touch to your face during wearing.
- Keep the mask flat and the inner surface to the upside after taking off, and fold it slightly and keep in the shade when necessary to avoid the breaking the nose clip.
- Do not use when you have dyspnoea or to sleep.
- Not recommend to the children under 3 years old.

AAB

PROTECTIVE BREATHING

MASK

Anti-fog/Anti-droplets/Anti-dust

Form QAT_10-M06, version 00, effective since March 25th, 2020

CE Documentation Review

No. 3E2003311T.HKM0503

Holder: Hunan Kanglilai Medi[illegible] Instrument Co., Ltd.
108 Longyang South Ro[illegible]munity, Canglang Street, Han[illegible]gde City, Hunan Province, C[illegible]

Review goal: Verification o[illegible] of Technical Documentat[illegible]h the Medical Devices D[illegible]nnex VII

Product: Me[illegible] (Non sterile)

Model(s):

Classification: [illegible]sterile)

Review [illegible]gly to the Manufacturer's [illegible]ation)

This document has been issued on a voluntary basis and upon request of the manufacturer. It is our opinion that the Technical Documentation shared with us by the manufacturer is compatible with the European Standard for Medical Devices.
Technical documentation identified with the no. CE-FM-(01-15).
The manufacturer is responsible for the CE Marking process, and not exempted to carry out all necessary compliance activities. This document has been issued on the basis of the regulation on ECM Voluntary Mark for the certification of products. RG01_ECM rev.3 available at: www.entecema.it

Date of issue 31 March 2020
Approver
ECM Service Director
Lucia Pedrini

Expiry date 30 March 2025
Technical Expert
Amanda Payne

CE

Declaration of Conformity

Manufacturer:
Name: Hunan Kanglilai Medical Instrument Co. , Ltd.
Add:108 longyang south road, bajiaolou community, cang[illegible]
hanshou county, changde city, hunan province.

Product Name : Medical face mask

Risk Class of the Device: The medical devic[illegible]d to class I , rule 1 according to ANNEX VIII, Medi[illegible]LATION (EU) 2017/745.

As a manufacturer, we declare that:
The product concerned has been des[illegible]ared under a quality management system according t[illegible]cal Device REGULATION (EU) 2017/745.
Following the procedure re[illegible]aration of Conformity set out in ANNEX IX of Medical [illegible]N (EU) 2017/745.

This Declaration [illegible]d in connection with the release document for the respect[illegible]d devices.

sentative:

ns Service & Consulting GmbH
Obere Seegasse 34/2, 69124,
berg, Germany
: +49 175 4870 819
Dimdi Code: DE/0000048234
E-mail: info@llins-service.com

Manufacturer: Fu Qiang

date:

Verification of Conformity

Applicant:	V&Q Manufacturing Corporation
Address:	#B1614 Optical Valley Times Square Guanshandad[illegible] Wuhan City, Hubei Province China
Product(s):	Surgical mask
Type(s):	VQN0185B-3, VQN0186G-3

The submitted sample of the above product has bee[illegible] the related European standards EN 14683:2014 Surgical Mask[illegible] methods.

Test Information:

Laboratory:	Nelson Laboratories, I[illegible]
Test Report(s) No.:	957829-S01, 94795[illegible]2-S01, 947953-S01
Type:	Bacterial Filtrati[illegible]ferential Pressure (Delta P) Microbial Cle[illegible]dical Masks Synthetic B[illegible]
Result:	Type IIR[illegible]

The test result and techni[illegible] listed devices is conformity with the requirements of Medica[illegible]ted standard.

SUNGO Ce[illegible]mited

Sungo

SUNGO
Executive Director
Issued: Jun.25 2019
Cert. No.: 2006US904518
Sungo
CERTIFIED