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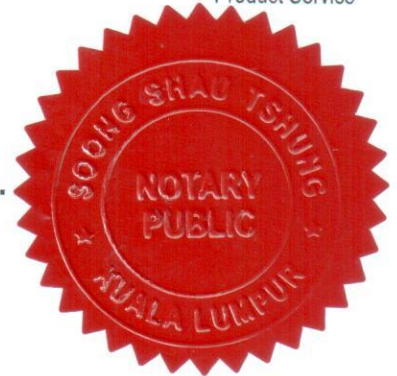
Product Service

# CERTIFICATE

No. Q1N 15 09 61155 010

**Holder of Certificate:** TERANG NUSA SDN. BHD.

1, Jalan 8, Pengkalan Chepa 2  
Industrial Zone  
16100 Kota Bharu, Kelantan  
MALAYSIA



**Facility(ies):**

TERANG NUSA SDN. BHD.  
1, Jalan 8, Pengkalan Chepa 2, Industrial Zone,  
16100 Kota Bharu, Kelantan, MALAYSIA



**Certification Mark:**



**Scope of Certificate:** Design and Development, Production and Distribution of Sterilized Surgical and Examination Gloves, Non-Sterile Examination Gloves and Sterile Radiation Reducing Surgical Gloves

**Applied Standard(s):**

EN ISO 13485:2012 + AC:2012  
Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2003 + Cor. 1:2009)  
DIN EN ISO 13485:2012

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.:** MYQMH0615067-721413143

**Valid from:** 2015-11-18

**Valid until:** 2018-10-31



This is to certify that the signature appears on this document/Certificate/ Marriage Certificate/Birth/Death Certificate is that of SOONG SHAU TSHUNG who is Notary Public Date: 2015-11-19  
The Ministry of Foreign Affairs, Malaysia is responsible for the accuracy of the information contained therein.

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Mohd Ridwan Mohd Nor  
Consular Officer  
Consular Division  
Ministry of Foreign Affairs  
Putrajaya Malaysia

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

TÜV SÜD Product Service GmbH · Ridlerstraße 65 · 80339 München · Germany



26 APR 2018

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ CERTIFICADO ◆ CERTIFICAT

**Dr. Ralph Derra**Öffentlich bestellter und vereidigter Sachverständiger für  
Verpackungsmaterialien, Boden- und Luftanalysen;  
Sachverständiger in der Wasseranalytik

21 January 2016

Dr. Dr/Ni-wei

**UNBEDENKLICHKEITSERKLÄRUNG  
CERTIFICATE OF COMPLIANCE  
CERTIFICAT DE CONFORMITE**eingetragen  
registered no.  
registré

41604 U 16

für Firma  
for Messrs  
pour MMAdventa Health Sdn. Bhd.  
No. 1, Jalan 8, Pengkalan Chepa 2, Industrial Zone  
16100 Kota Bharu, Kelantan  
MalaysiaProdukt  
Product  
Produit

Nugard Nitrile PF

The nitrile gloves manufactured by the company mentioned above are used in the food industry for the preparation and handling of foodstuffs.

They were examined by us according to the

Methoden zur Untersuchung von Kunststoffen, soweit sie als Bedarfsgegenstände im Sinne des Lebensmittel- und Bedarfsgegenständegesetzes verwendet werden, einschließlich der 62. Mitteilung des BfR zur Untersuchung von Hochpolymeren, Bundesgesundheitsblatt 50, 524 (2007), Stand vom April 2007,

(Methods for testing plastics as far as they are used as consumer goods as defined by the Foodstuffs and Consumer Goods Act, including the 62<sup>nd</sup> memorandum of the BfR on the examination of high polymers, Bundesgesundheitsblatt 50, 524 (2007), state of April 2007),

for the composition as well as for the release of substances which might endanger health and to the

- 2 -

"Methoden zur Untersuchung von Bedarfsgegenständen, Grundregeln für die Ermittlung der Migration in Prüflebensmittel", entsprechend der Vorschrift Nr. 80.30, 1 - 3 (EG) in der Amtlichen Sammlung von Untersuchungsverfahren nach § 64 des Lebensmittel- und Futtermittelgesetzbuchs - LFGB, Stand vom April 2008,

("Methods for the examination of consumer goods, basic rules for the determination of the migration into food simulants", according to the standard no. 80.30, 1 - 3 (EC) within the Official Collection of Testing Methods according to § 64 of the Foodstuffs and Animal Feed Code - LFGB, state of April 2008),

as well as to the

Series of standards EN 1186, EN 13130 and CEN/TS 14234 „Materials and Articles in Contact with Foodstuffs - Plastics“, current state,

for the migration behaviour.

The nitrile gloves are in compliance with the rules of the

Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC, Official Journal of the European Union L 338/4 of 13.11.2004, modified by app. no. 5.17 of the regulation (EC) No 596/2009 of 18 June 2009, Official Journal of the European Union L 188 of 18 July 2009, article 3,

as well as of the

Lebensmittel-, Bedarfsgegenstände- und Futtermittelgesetzbuch (Lebensmittel- und Futtermittelgesetzbuch - LFGB) in der Fassung der Bekanntmachung vom 3. Juni 2013 (BGBl. I S. 1426), zuletzt geändert durch Artikel 67 der Verordnung vom 31. August 2015 (BGBl. I S. 1474), §§ 30 und 31,

(Foodstuffs, Consumer Goods and Animal Feed Code (Foodstuffs and Animal Feed Code - LFGB) in the version of the notification of 3 June 2013 (BGBl. p. 1426), last amendment by article 67 of the law of 31 August 2015 (BGBl. I p. 1474), §§ 30 and 31).

They meet the demands of the

Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food, Official Journal of the European Union L 12/1 of 15 January 2011, last amendment by Commission Regulation (EU) No 2015/174 of 5 February 2015, Official Journal of the European Union L 30/2 of 6 February 2015,

with regard to the migration behaviour and are approved according to the

Deutsche Empfehlung XXI zur gesundheitlichen Beurteilung von Materialien und Gegenständen für den Lebensmittelkontakt im Rahmen des Lebensmittel- und Futtermittelgesetzbuches, 13. Mitteilung, Bundesgesundheitsblatt 5, 403 (1962), einschließlich 219. Mitteilung, Bundesgesundheitsblatt 58, 1195-1197 (2015), Stand vom 01.07.2015,

(German Recommendation XXI for the health-related evaluation of materials and objects for the contact with foodstuffs in the frame of the Foodstuffs and Animal Feed Code, 13<sup>th</sup> memorandum, Bundesgesundheitsblatt 5, 403 (1962), including the 219<sup>th</sup> memorandum, Bundesgesundheitsblatt 58, 1195-1197 (2015), state of 1 July 2015).

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Thus, the nitrile gloves Nugard Nitrile PF according to the sample material submitted may be used safely for the preparation and handling of foodstuffs and may stand in direct contact with all types of food for a short period of time. The ratio of the food contact surface of the gloves and the mass of the food shall not exceed 8.4 dm<sup>2</sup> per 5 kg food.

This certificate of compliance has a validity of 2 years and consists of 4 pages.

staatlich anerkannter Sachverständiger  
zur Untersuchung der Gegenproben von  
Verpackungsmitteln aus Papier, Pappe,  
Kunststoffen, Glas, Weißblech und  
sonstigen Metallverpackungen auf ihre  
Lebensmittelrechtliche Unbedenklichkeit



(Behrendt)  
Officially certified  
and authorized food  
chemist



The translation of the above stamps is given on page 4.  
La traduction des estampilles est donnée en page 4.



**Staatlich anerkannter Sachverständiger zur Untersuchung der Gegenproben von Verpackungsmitteln aus Papier, Pappe, Kunststoffen, Glas, Weißblech und sonstigen Metallverpackungen auf ihre lebensmittelrechtliche Unbedenklichkeit**

Dr. Ralph Derra

Authorized expert for the analyses of packaging materials, attested by the Aschaffenburg Chamber of Industry and Commerce.

Expert autorisé pour l'analyse des matériaux d'emballage, assermenté par la Chambre d'Industrie et de Commerce d'Aschaffenburg.

State registered expert for the analysis of contrasting samples of packaging materials of paper, board, plastics, glass, tin plate and other metallic packaging materials as to their suitability for use with food-stuffs.

Expert public pour l'étude du control des contre-échantillons d'emballages de papier, cartons, plastiques, verre, fer-blanc et d'autres emballages métalliques concernant leur conformité alimentaire.



Dr. Ralph Derra

Authorized expert for the analyses of soil and air, attested by the Aschaffenburg Chamber of Industry and Commerce.

Expert autorisé pour l'analyse du sol et de l'air, assermenté par la Chambre d'Industrie et de Commerce d'Aschaffenburg.

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Die Rücklagen des untersuchten Materials werden bei der Gutachterstelle verwahrt.  
A file sample of the tested material is kept at the expert's office.  
Réserve du matériel analysé est gardée au bureau de l'expert.

TERANGNUSA (M) SDN BHD  
 PLO 9 & 18, KWSN PERINDUSTRIAN KLUANG  
 86007 KLUANG, JOHOR, MALAYSIA  
 TEL : 07-7879812

## Certificate of Analysis

Consignee : Issued date : 29/06/2015  
 Type of gloves : ENDBHF32 Invoice No. :  
 Exam. Nitrile, Powder Free Gloves Order No. :  
 Certificate No. : 001/15

Test Performed	Standard EN 455	Results
Inspection Plan ISO2859		
Watertight test failures(1000ml) GI AQL 1.5	500 – 14 – 15	6
Dimension Length (mm) S2 AQL 4.0	>= 240	242 – 246
Width (mm) XS	NA	NA
S	NA	NA
M	95 ± 10	96
L	NA	NA
XL	NA	NA
Thickness (mm) Cuff	NA	0.05 – 0.06
Palm	NA	0.06 – 0.07
Finger	NA	0.09 – 0.10
Force at break throughout shelf life S2 AQL 4.0		
Force at break (median)	Min. 6.0 N	6.972 N
Force at break after challenge testing S2 AQL 4.0		
Force at break (median)	Min. 6.0 N	6.817 N

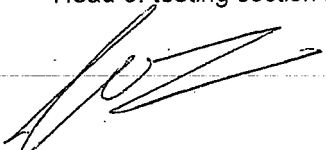
- \* Force @ break after challenge testing carried out as per EN 455 part 2 at 70°C for 7 days.
- \* The inspection plan is following according to ISO 2859 GI AQL 1.5 (Water tight test) S2 AQL 4.0 (Others)

Protein content	Test Standard EN455-3	NA
Powder content	Max. 2.0 mg/glove	1.00 mg/glove

Note :

Lot No :	NA
Manufacturing date :	2015-06
Expiry date :	2020-05

Head of testing section :



Vincent Chua Kim Chok  
 QA Manager

**UNCONTROLLED  
 DOCUMENT**  
 (For Reference Only)