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# W.A. RUBBERMATE CO., LTD







4 SOI RAMKHAMHAENG 19 (CHAREONPLOY)
RAMKHAMHAENG ROAD, HUAMARK
BANGKAPI, BANGKOK 10240, THAILAND

# CE EU DECLARATION OF CONFORMITY According to the Medical Device Directive 93/42/EEC EU DECLARATION OF CONFORMITY According to the Medical Device Directive 93/42/EEC

Manufacturer's Name : W.A. RUBBERMATE CO., LTD

Manufacturer's Address : 4 SOI RAMKHAMHAENG 19 (CHAREONPLOY),

RAMKHAMHAENG ROAD, HUAMARK, BANGKAPI,

BANGKOK 10240, THAILAND

Quality Management System : ISO 9001:2008, ISO 13485: 2003

Name of Device : Nitrile Examination Gloves

Type : Powder Free Classification : Class I, Non Sterile

Conformity Route : Annex VII

We herewith declare in our own responsibility that the above-mentioned product(s) with CE mark meet the provisions of the EC Council Directive 93/42/EEC 14th June 1993 concerned medical devices, amended by Council Directive 2007/47/EC. All supporting documentations are retained under the premise of the manufacturer (Head of Quality department).

## General applicable directives:

Council Directive 93/42/EEC 14th June 1993 concerned medical devices, amended by Council Directive 2007/47/EC.

For evaluation of the compliance with these Directives, the following standards were applied:

- EN-455 Parts I, II, III
- EN-374 Parts I, II, III
- ISO 2859-1-99
- ASTM D6319-99

Name of Signatory: Benchamad Kongwaree
Title: Managing Director
Date: 31 January 2013

Signature: Stamp of the Manufacturer





# **NITRILE EXAMINATION GLOVES**

This Product Does Not Contain Any Natural Rubber Latex

## **MATERIAL SAFETY DATA SHEET**

## **IDENTIFICATION**

Product Name : W.A. Rubbermate Co., Ltd Product : Nitrile Examination Gloves

Lightly Powdered and Powder Free

Case # : Not Established IATO / IACO : Not Restricted Hazard Rating : Not Restricted D.O.T. Rating : Not Restricted

#### **PHYSICAL DATA**

Nitrile Butadiene Rubber : 95.8% Sulfur : 1% Zinc Oxide : 1.2% Accelerators : 1% Others : 1%

Donning Agent : Food Grade Absorbable Dusting Powder USP Cornstarch

(Powdered Nitrile Examination Gloves Only)

# **FIRE AND EXPLOSION**

Stability : Stable Flash Point : N.A.

Extinguishing Media : Foam, Carbon Dioxide, Water

# **NORMAL PRECAUTIONS**

Ventilation : Not necessary under normal conditions.

Equipment : Not necessary

Spill / Clean Up : N/A Eyes : N/A

Storage : No special precautions necessary

Store at room temperature



Notified Body 0321

Issued to: W.A. Rubbermate Co., Ltd

67/1 Moo4, Bypass Road T. Nongmaidaeng, Muang,

Chonburi 20000. **Thailand** 

SATRA Client: P1436

# EC Type-Examination Certificate

# Number 7642 Issue 1 Extension 1

This is to certify that the product group reference NBR-FT-35 comprising the following products

**Product Reference** 

Description

NBR-FT-35

Five fingered Blue powder free Nitrile gloves

Sizes 7-10

Classification:

| EN 388:2003          | Level | EN 374-2:2003 |      |
|----------------------|-------|---------------|------|
| Abrasion resistance  | 0     | Air Leak      | Pass |
| Blade cut resistance | 0     | Water Leak    | Pass |
| Tear resistance      | 0     |               |      |
| Puncture resistance  | 0     |               |      |

| EN 374-3:2003        | Level |  |
|----------------------|-------|--|
| Sodium Hydroxide 40% | 6     |  |
| n-Heptane            | 0     |  |
| Methanol             | 0     |  |

**Technical reports** 

SATRA: SPC0221961/1406/1, CHM0229406/1443/EN, SPC0221961/1406/SMcD

has been subject to an EC Type-examination in accordance with Article 10 of the PPE Directive (89/686/EEC) and has been shown to satisfy the relevant provisions of this Directive for the complex category through:

- Testing to the following standard: EN 374-1:2003 (Excluding clause 5.3.2), EN388:2003, EN420:2003+A1:2009
- Examination of the relevant technical documentation.

You are therefore licensed to mark the product(s) listed above in accordance with Article 13 of Directive (89/686/EEC) and any relevant amending Directives once you have drawn up an EC declaration of product conformity. Please note that:

- 1. Full details of the certification and product are contained in the manufacturer's technical file
- 2. This certificate is only valid if embossed with the text "SATRA European Notified Body 0321"
- 3. This certificate is issued subject to the conditions on the reverse side of this certificate
- 4. CE marking of production is also reliant on current compliance with Directive 89/686/EEC Article 11

(T. Holly)

Signed:

Carabolly .

Date: 20th February 2015

On behalf of SATRA





