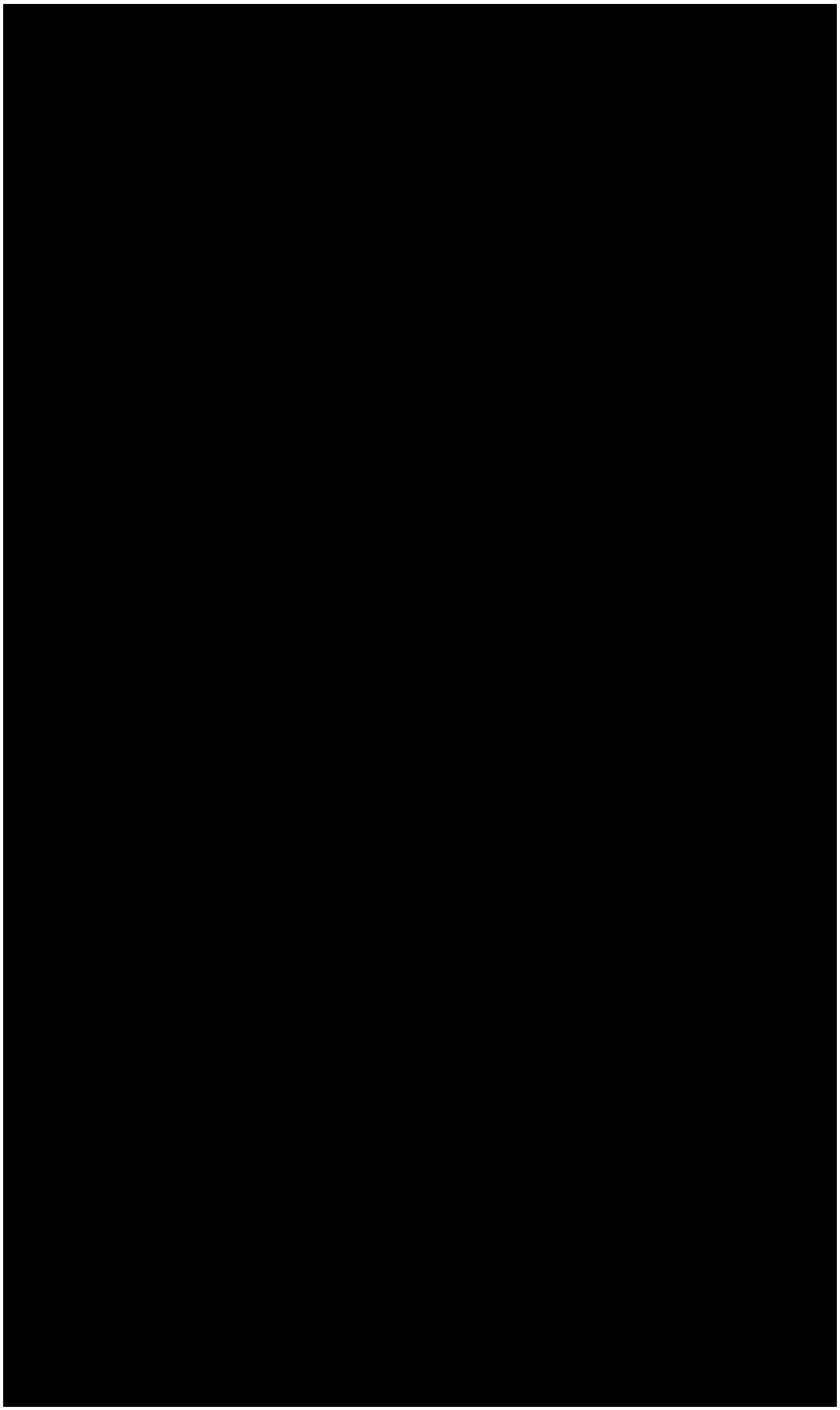
Polycare Examination Gloves,
Powder-free Documentation

Meditech

Content

1. Polycare Product Sheet with Picture



2. CE Marking

bsi.

By Royal Charter

EU Type Examination Certificate

This is to certify that:

Meditech Gloves Sdn. Bhd.
PT 3345, Jalan Permata 1/3
Arab Malaysian Industrial Park
Nilai
Negeri Sembilan, Darul Khusus
71800
Malaysia

Holds Certificate Number: CE 698568

In respect of:

Natural rubber gloves for personal protection- models MEPF3 & MSPF2
(NBR) Nitrile Butadiene Rubber Latex gloves for personal protection- model MNEPF1.
To EN 420:2003+A1:2009, EN ISO 374-1:2016 & EN ISO 374-5:2016.

on the basis that BSI carried out the relevant Type Examination procedures under the requirements with the Regulation (EU) 2016/425 of the European Parliament and Council relating to Personal Protective Equipment Regulation (PPE) Annex V (Module B) and meets the relevant health and safety requirements specified in Annex II

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 0086):

Chris Lewis - Certification Director, Product Certification

First Issued: 2019-05-02
Latest Issue: 2019-07-31

Effective Date: 2019-07-31
Expiry Date: 2024-05-02

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EU Type Examination Certificate

No. CE 698568

Product Specification:

The PPE equipment Protective Gloves that are covered by the scope of this Module B Certificate and the Harmonized European Standards and technical specifications to which the products are approved are to the following specifications:

Model:	**MEPF3 Polycare Latex Examination Gloves**
Classification:	Protective gloves for use against microorganisms and general applications.
Description:	Natural rubber latex examination gloves, powder free and non-sterile. Ambidextrous gloves with beaded cuff, available in off-white to light yellow colours.
Size Range:	XS to XL
Product codes:	MEPF3-XS, MEPF3-S, MEPF3-M, MEPF3-L and MEPF3-XL.

Product Specification

Performance:

Resistance to penetration to EN 374-2:2014
Pass

Resistance to degradation to EN 374-4:2013
Tested for degradation against the chemical listed below.
Sodium Hydroxide 40% (CAS:1310-73-2)
Mean Degradation: -84.3%

Resistance to chemical permeation to EN ISO 374-1:2016 (Test method EN 16523-1:2015) **Type C**

Chemical	**Level**
Sodium Hydroxide 40% (K)	6

General requirements for gloves to EN 420:2003+A1:2009

Dexterity:	Level 5
pH:	7.5
Protein Content:	84.5 µg/g

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EU Type Examination Certificate

No. CE 698568

Product Specification continued:

Model: **MSPF2 - ExcellPC Sterile Latex Surgical Gloves Powder Free**

Classification: Protective gloves for use against microorganisms and general applications.

Description: Natural rubber latex sterile polymer coated Surgical Gloves, powder free, disposable single use, sterilized by Gamma Irradiation, beaded cuff and anatomical shape., available in off-white to light yellow colours.

Size Range: 5.5 to 9.0

Product codes: MSPF2-5.5, MSPF2-6.0, MSPF2-6.5, MSPF2-7.0, MSPF2-7.5, MSPF2-8.0, MSPF2-8.5 and MSPF2-9.0.

Product Specification

Performance:

Resistance to penetration to EN 374-2:2014
Pass

Resistance to degradation to EN 374-4:2013
Tested for degradation against the chemical listed below.
Sodium Hydroxide 40% (CAS:1310-73-2)
Mean Degradation: -78.9%

Resistance to chemical permeation to EN ISO 374-1:2016 (Test method EN 16523-1:2015) **Type C**

Chemical	Level
Sodium Hydroxide 40% (K)	6

General requirements for gloves to EN 420:2003+A1:2009

Dexterity: Level 5
pH: 7.2
Protein Content: 123.5 µg/g

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EU Type Examination Certificate

No. CE 698568

Product Specification continued:

Model:	**MNEPF1 – BPG Nitrile Examination Gloves Powder-free**
Classification:	Protective gloves for use against microorganisms and general applications.
Description:	NBR (Nitrile Butadiene Rubber Latex) examination gloves, powder free and non-sterile. Ambidextrous gloves with beaded cuff, available in blue colour.
Size Range:	XS to XL
Product codes:	MNEPF1-XS MNEPF1-S, MNEPF1-M, MNEPF1-L and MNEPF1-XL.

Product Specification

Performance:

Resistance to penetration to EN 374-2:2014
Pass

Resistance to degradation to EN 374-4:2013
Tested for degradation against the chemical listed below.
Sodium Hydroxide 40% (CAS:1310-73-2)
Mean Degradation: -21.6%

Resistance to chemical permeation to EN ISO 374-1:2016 (Test method EN 16523-1:2015) **Type C**

Chemical	**Level**
Sodium Hydroxide 40% (K)	6

General requirements for gloves to EN 420:2003+A1:2009

Dexterity:	Level 5
pH:	6.2
Protein Content:	N/A

First Issued: 2019-05-02
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Expiry Date: 2024-05-02

EU Type Examination Certificate

No. CE 698568

Applicable Standards:

The following Harmonized European Standards:

EN 420:2003+A1:2009 Protective gloves. General requirements.

EN ISO 374-1:2016. Protective gloves against dangerous chemicals and micro-organisms. Terminology and performance requirements for chemical risks.

EN 374-2:2014. Protective gloves against dangerous chemicals and microorganisms. Determination of resistance to penetration.

EN 374-4:2013. Protective gloves against chemicals and micro-organisms. Determination of resistance to degradation by chemicals.

EN ISO 374-5:2016. Protective gloves against dangerous chemicals and micro-organisms. Terminology and performance requirements for micro-organisms risks.

EN 16523-1:2015. Determination of material resistance to permeation by chemicals. Permeation by liquid chemical under conditions of continuous contact.

First Issued: 2019-05-02
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Effective Date: 2019-07-31
Expiry Date: 2024-05-02

EU Type Examination Certificate

No. CE 698568

Certificate Administration Details

Manufacturer's technical file reference: MEPF3 v1, MSPF2 v0 and MNEPF1 v0 Technical Files.

Certificate Amendment Record:

Issue Date	Comments	Internal BSI Project Number
April 2019	Transition of PPE Directive, Article 10 CE 684183. Model: MEPF3. Addition on new models MNEPF1 & MSPF2.	0086:19:9640615
July 2019	Addition of sizes XS & XL to MNEPF1	0086:19:3043355

Note: The Certificate holder is responsible for ensuring that the Notified Body is advised of changes to any aspect of the overall processes utilised in the manufacture of the product, failure to do so could invalidate the Certificate in respect of product manufactured following the introduction of such changes.

Monitoring of manufactured PPE:
The validity of the Certificate is also dependent on the conformity to the type based on the internal production control plus supervised product checks at random intervals (Annex VII, Module C2), for the specific standards/product that are referenced in the BSI issued Module C2 Certificate Number CE 615886.

First Issued: 2019-05-02
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Effective Date: 2019-07-31
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

Dr. Effendi Tenang
Managing Director
Best Putra Gloves SDN BHD
Lot 1357-1358, JLN Kg. Mohd Taib
Kawasan Perindustrian Sg. Choh
48000 Rawang, Selangor Darul Ehsan, Malaysia

NOV 10 2010

Re: K101105
Trade/Device Name: Powder-Free, Latex Examination Glove, Natural Color, Non-Sterile, Model: MEPF1
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LYY
Dated: October 4, 2010
Received: October 21, 2010

Dear Dr. Tenang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

[redacted]

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

BEST PUTRA GLOVES SDN.BHD. (580515-T)
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Tel: +03-6092 1042, +03-6092 1142 Fax: +03-6091 2820
E-mail: bpg@streamyx.com Website : www.bpgloves.com

K101105

NOV 10

INDICATIONS FOR USE

510(k) Number: K101105

Device Name: Powder – Free, Latex Examination Glove, Natural Color, Non-Sterile, Model: MEPF1

Indications For Use:

A powder-Free patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

Si[redacted]

Dr. Effendi Tepang
(Managing Director)

Prescription Use_____
(Part 21 CFR 801 Subpart D)

OR

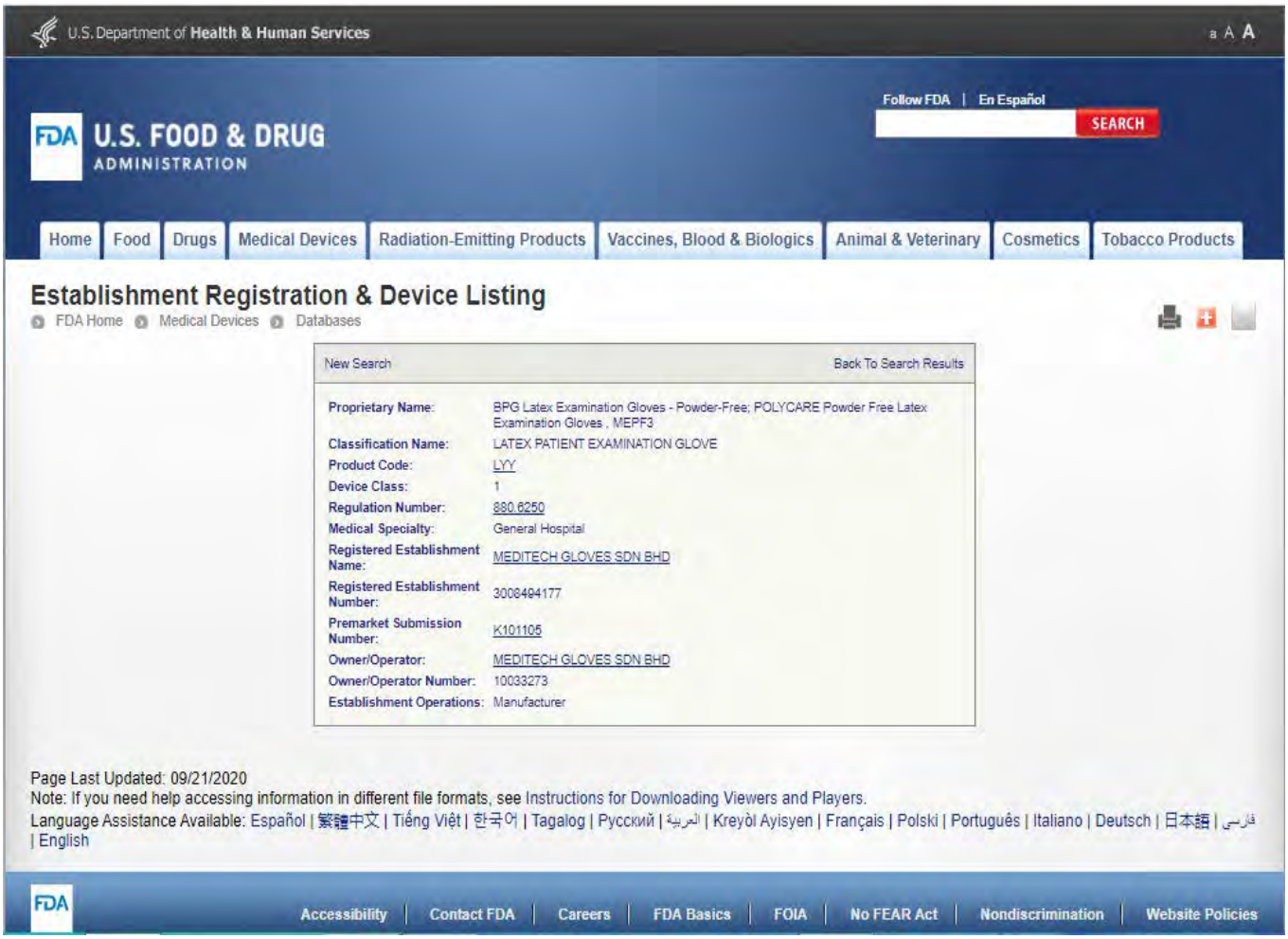
Over – The – Counter Use _XXX____
(21 CFR 801 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

[redacted]
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K101105

4. FDA Certificate



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Proprietary Name:	BPG Latex Examination Gloves - Powder-Free; POLYCARE Powder Free Latex Examination Gloves , MEPF3
Classification Name:	LATEX PATIENT EXAMINATION GLOVE
Product Code:	LYY
Device Class:	1
Regulation Number:	880.6250
Medical Specialty:	General Hospital
Registered Establishment Name:	MEDITECH GLOVES SDN BHD
Registered Establishment Number:	3008494177
Premarket Submission Number:	K101105
Owner/Operator:	MEDITECH GLOVES SDN BHD
Owner/Operator Number:	10033273
Establishment Operations:	Manufacturer

Page Last Updated: 09/21/2020

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www.satra.co.uk

UKAS TESTING 0248

Customer details: BSI Group
PO Box 6221
Kitemark Court
Davy Avenue
Milton Keynes
MK1 9EP

For the attention of: Kinga Demetriou

SATRA reference: SPC0253226/1701/ SMcD/A

Your reference: 4500095154.

Date of report: 1st March 2017

Samples received: 5th January 2017

Date(s) work carried out: 16th to 22nd February 2017

TECHNICAL REPORT

Subject: Chemical innocuousness testing in accordance with BS EN 420: 2003 + A1: 2009 on gloves described as MEPF3

Conditions of Issue:

This report may be forwarded to other parties provided that it is not changed in any way. It must not be published, for example by including it in advertisements, without the prior, written permission of SATRA.

Results given in this report refer only to the samples submitted for analysis and tested by SATRA. Comments are for guidance only.

Tests marked ≠ fall outside the UKAS Accreditation Schedule for SATRA. All interpretations of results of such tests and the comments based upon them are outside the scope of UKAS accreditation and are based on current SATRA knowledge.

A satisfactory test report in no way implies that the product tested is approved by SATRA and no warranty is given as to the performance of the product tested. SATRA shall not be liable for any subsequent loss or damage incurred by the client as a result of information supplied in the report.

The uncertainty of the results (UoM) in this report is based on a standard uncertainty multiplied by a coverage factor k=2, which provides for a confidence level of approximately 95%.

Report signed by: S McDonald
Position: Chemical Technologist
Department: Chemical & Analytical Technology

[redacted]

[redacted]

Signed: [redacted]

TERMS AND CONDITIONS OF BUSINESS

[redacted]

Issue Date: 1st October 2009

SATRA Technology Centre Ltd
Wyndham Way, Telford Way, Kettering,
Northamptonshire, NN16 8SD United Kingdom
Tel: +44 (0) 1536 410000
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www.satra.co.uk

UKAS TESTING 0248

Customer details: BSI Group
PO Box 6221
Kitemark Court
Davy Avenue
Milton Keynes
MK1 9EP

For the attention of: Kinga Demetriou

SATRA reference: SPC0253226/1701/ SMcD/B

Your reference: 4500095154.

Date of report: 2nd March 2017

Samples received: 5th January 2017

Date(s) work carried out: 20th to 22nd February 2017

TECHNICAL REPORT

Subject: BS EN 16523-1:2015 resistance to permeation by chemicals on gloves described as MEPF3 against 40% sodium hydroxide

Report signed by: S McDonald
Position: Chemical Technologist
Department: Chemical & Analytical Technology

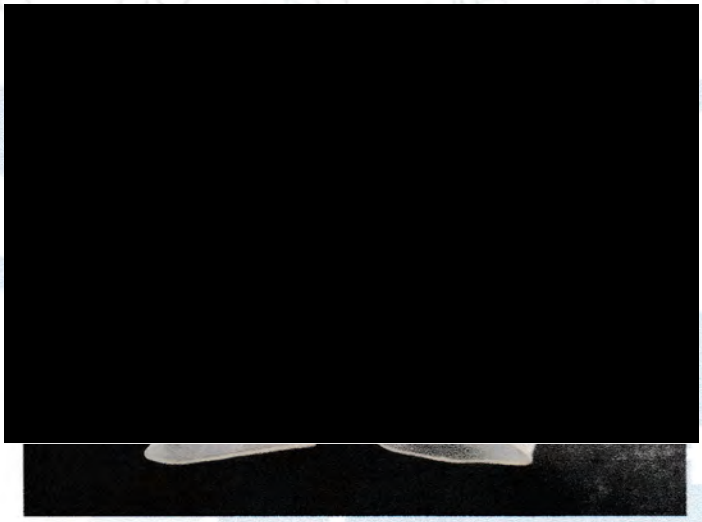
WORK REQUESTED:

[redacted]

[redacted]

Signed: [redacted]

APPENDICES:



Gloves described as MEPF3

TERMS AND CONDITIONS OF BUSINESS

[redacted]

Issue Date: 1st October 2009

Signed: [redacted]

SATRA Technology Centre Ltd
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UKAS TESTING 0248

Customer details: BSI Group
PO Box 6221
Kitemark Court
Davy Avenue
Milton Keynes
MK1 9EP

For the attention of: Kinga Demetriou

SATRA reference: SPC0253226 /1701 /1

Your reference: 4500095154.

Date of report: 6 March 2017

Samples received: 5 January 2017

Date(s) work carried out: 2 March 2017

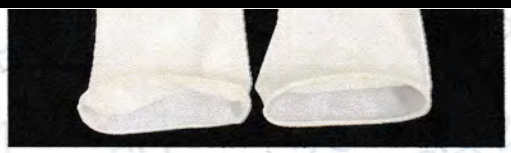
TECHNICAL REPORT

Subject: Testing of gloves identified as MEPF3 in accordance with EN 420: 2003 + A1: 2009 clauses 5.1 Sizing and 5.2 Dexterity only and EN 374-2: 2014.

Report signed by: Adam Mortiboys
Position: PPE Technologist
Department: Safety Product Testing

Work Requested

[redacted]



MEPF3

Conclusion

[redacted]

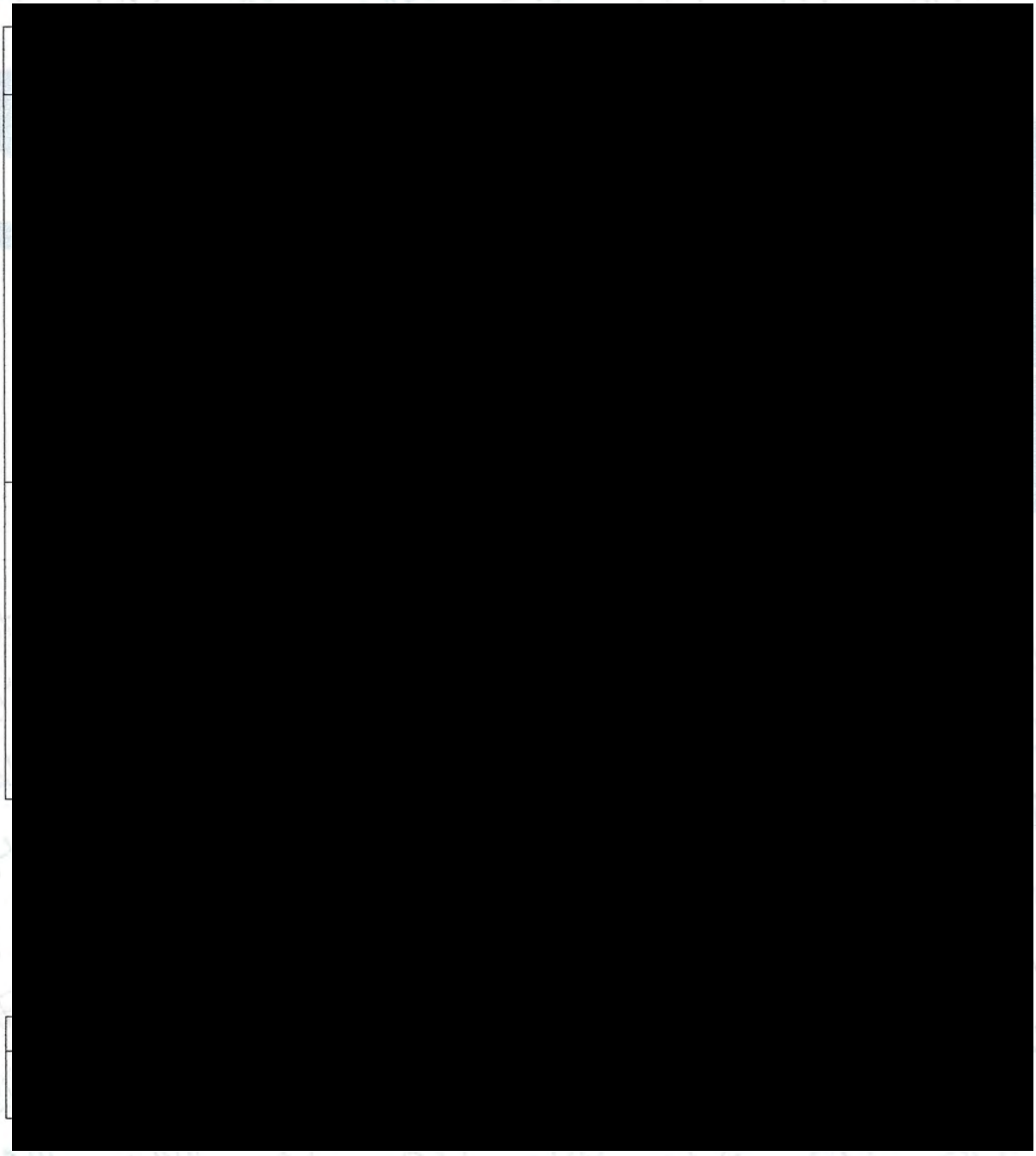
Note ▲ – Where gloves do not meet the minimum length requirements specified in Table 1 of EN 420:2003 + A1:2009, the standard therefore requires that the manufacturer shall clearly state in the user instructions the intended application of the gloves and the reason why the gloves do not conform to the minimum length requirements.

Note ♦ – As per clause 4.3 of EN 374-2:2014, the gloves submitted for testing were found to be unsuitable for the Air leak test. Therefore as per EN 374-2 only the Water leak test has been performed.

Testing

[redacted]

EN 374-2: 2014 Test Results



TERMS AND CONDITIONS OF BUSINESS

1. [redacted]
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Issue Date: 1st October 2009

Surgical Material Testing Laboratory

Test Report

Examination Glove Report

Report No: 19/5988/1

Report Date: Wednesday 6th November, 2019

Authors:
Louise Barry
Fara Shadroo

Revision Information:
Template Version: 339a63c
Revision: 1.4
Revision date: Wednesday 6th November, 2019
Revision Author: louise

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ilac-MRA UKAS TESTING 1492

Examination Glove Report
Report No: 19/5988/1

Louise Barry
Fara Shadroo

Wednesday 6th November, 2019

1 Name & Address of Client/Requesting Authority

Paddy Smyth (Best Putra)
Managing Director (Best Putra)
Wan Nadzifah Binti Wan Hassan
QA Manager (Acting)
Meditech Gloves Sdn Bhd
PT 3345, Jln. Permata 1/3,
Arab Malaysian Industrial Park,
71800 Nilai, Negeri Sembilan,
Malaysia

Email: pjsmyth@bpgloves.co.uk
nadzifah@meditechgloves.com.my
michael@bpgloves.co.uk
aminkassim@gmail.com

2 Introduction

This document presents the results of POLYCARE Latex Examination Gloves tested to BS EN 455 Parts 1[(1)] and 3 Total Extractable Protein[(2)].

3 Test Products/Samples for this project

Table 1: Samples

Supplier	Product Name	Description	Catalogue Number	Batch/Lot Number	Quantity	Date received	SMTL Sample ID
Meditech Gloves	POLYCARE	Latex Examination Gloves Powder Free, Size Medium, DOM 09-2019	MEPF3-M	31938010 9	400	04/10/2019	60869

NOTES:

- The test results in this report relate only to the test sample(s) analysed.
- The Manufacturer, Product Name, Description, Catalogue & Batch Numbers were provided by the client.

3.1 Departures/Abnormalities of Sample Condition

None.

4 Date of Testing

8th - 10th October 2019.

5 Location of Testing

All testing was performed at SMTL premises

6 Testing Details

6.1 Perforations - TM-22[3]

6.2 Extractable protein - TM-230[4]

[redacted]

6.3 Standards relevant to the test method

[redacted]

6.4 Testing conditions

6.4.1 Perforations

- [redacted]

6.4.2 Total Extractable Protein

- [redacted]

6.5 Deviations/exclusions from, and additions to standard methods

6.5.1 Perforations

- None.

6.5.2 Total Extractable Protein

- None.

6.6 Uncertainty of Measurement

Uncertainty of measurement (UoM) has not been taken into account when interpreting the test results.

6.7 Sampling Details

All samples were selected and supplied by the client.

The batch size of the gloves supplied was not stated by the client. In accordance with BS EN 455 Part 1, a batch size between 35,001 to 150,000 was chosen, and therefore 50 gloves per stage were tested for perforations using General Inspection Level I at an AQL of 1.5%. With reference to Table 3, the sample size was tested up to the fifth sampling stage or until compliance or non compliance was determined.

6.8 Sample Preparation

Samples were prepared according to the relevant test method used.

7 Results

7.1 Perforation Testing

The results of perforation testing are presented in Table 2. Compliance has been determined with reference to Table 3.

Table 2: Perforation Testing results for Sample 60869

Note:

- Perforations were detected in the palm (4 gloves), finger (2 gloves), thumb (2 gloves) and 1 glove had 4 perforations in the palm.

Table 3: Multiple sampling - Perforation compliance (BS EN 455-1)

7.2 Total Extractable Protein

The total amount of extractable protein per gram for each of the inner and outer surface test samples is presented in Table 4.

Table 4: Total Extractable Protein results for Sample 60869

† Ovalbumin Equivalent Protein

8 Authorisation

Approved and signed electronically. Please see last page of this document.

Pete Phillips, Director, SMTL.

References

(1) *Medical gloves for single use - part 1: Requirements and testing for freedom from holes. BS EN 455-1:2000*.

(2) *Medical glove for single use - part 3: Requirements and testing for biological evaluation. Annex A:Method for the determination of aqueous extractable proteins in natural rubber gloves using the modified lowry assay. BS EN 455-3:2015*.

(3) SMTL. *Detection of perforations in medical gloves to BS EN 455 Part 1*. (TM-22).

(4) SMTL. *Determination of extractable protein in natural rubber gloves*. (TM-230).

LEMBAGA GETAH MALAYSIA
MALAYSIAN RUBBER BOARD
RUBBER RESEARCH INSTITUTE OF MALAYSIA
Global Testing and Consultancy for Rubber (G-TACR)

Malaysian Rubber Board, 47000 Sungai Buloh, Selangor.
Tel: (6)03-61459471 Fax: (6)03-61412907
Email: gtacr@lgm.gov.my Website: http://www.lgm.gov.my/gtacr

G-TACR A Service by MRB
GLOBAL TESTING AND CONSULTANCY FOR RUBBER

ilac-MRA

STANDARDS MALAYSIA
MS ISO/IEC 17025
TESTING/CALIBRATION
SAMM NO.008

September 6, 2016

Our Report No : **LGM/BTK/UPB/5.10/CP/1609/0004**
Your Reference :

MEDITECH GLOVES SDN BHD
Lot 3345, Jalan Permata 1/3,
Arab Malaysia Industrial Park,
71800 Nilai, Negeri Sembilan Darul Khusus,
Malaysia. **Fax : 606-7997749**

Attention : Nurul Izwana Azman

ANALYTICAL TEST REPORT OF EXTRACTABLE ANTIGENIC CONTENT

We have received samples delivered to us under your cover letter dated July 28, 2016. Analysis had been carried out as per your request. Samples were extracted with Phosphate Buffered Saline (5 ml PBS per gram sample) following the extraction procedure of ASTM D5712-10. We report the following results :

Date of receipt of sample : September 1, 2016
Date Tested : September 6, 2016
Test Method : ASTM D6499-07
Sample Condition : Unaged
Type of Sample : Glove

Sample Reference	Protein Content µg/g
1. Latex Examination Gloves, Powder-Free (Polymer Coated) Lot no. : 316290110	ND

Note : ND means not detected at limit of detection of 1 µg/g

[redacted]
Rumida Ab. Rahim
(IKM No.: A2542/5226/07)
Research Officer
Malaysian Rubber Board
For Director General

LEMBAGA GETAH MALAYSIA
MALAYSIAN RUBBER BOARD
RUBBER RESEARCH INSTITUTE OF MALAYSIA
Global Testing and Consultancy for Rubber (G-TACR)
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Tel: (6)03-61459471 Fax: (6)03-61412907
Email: gtacr@lgm.gov.my Website: http://www.lgm.gov.my/gtacr

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STANDARDS MALAYSIA
MS ISO/IEC 17025
TESTING/CALIBRATION
SAMM NO.008

Our report no. : LGM/BTK/UPB/5.10/CP/1609/0005

Your reference : -

MEDITECH GLOVES SDN. BHD.
PT 3345, JALAN PERMATA 1/3,
71800 NILAI, NEGERI SEMBILAN DARUL KHUSUS,MALAYSIA,
(ATTN : NURUL IZWANA AZMAN) Fax No.: 06-677 9620

ANALYTICAL RESULT

We have received one sample from you under covering letter dated 28/07/2016 . The sample was analyzed as per your request. The results are reported below.

Sample Description : LATEX EXAMINATION GLOVES, POWDER FREE (POLYMER COATED) LOT NO : 316290110

Date Received : 01/09/2016

[redacted]

[redacted]

[redacted]

LEMBAGA GETAH MALAYSIA
MALAYSIAN RUBBER BOARD
RUBBER RESEARCH INSTITUTE OF MALAYSIA
Global Testing and Consultancy for Rubber (G-TACR)
Malaysian Rubber Board, 47000 Sungai Buloh, Selangor.
Tel: (6)03-61459471 Fax: (6)03-61412907
Email: gtacr@lgm.gov.my Website: http://www.lgm.gov.my/gtacr

G-TACR A Service by MRB
GLOBAL TESTING AND CONSULTANCY FOR RUBBER

ilac-MRA

STANDARDS MALAYSIA
MS ISO/IEC 17025
TESTING/CALIBRATION
SAMM NO.008

Our report no. : LGM/BTK/UPB/5.10/CP/1609/0005

"BERKHIDMAT UNTUK NEGARA"

[redacted]
Kartini Alias
(IKM NO : M2541/5225/07)
Research Officer
Malaysian Rubber Board
For Director-General

Date of reporting
28 SEPTEMBER 2016

8. ISO 13485: 2016 Certificate

bsi.

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Meditech Gloves Sdn. Bhd.
Lot 3345, Jalan Permata 1/3
Arab Malaysian Industrial Park
71800 Nilai
Negeri Sembilan, Darul Khusus
Malaysia

Holds Certificate No: **MD 631470**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

The manufacture of powdered and powder-free sterile latex surgical gloves, powder-free sterile latex surgical under gloves and examination gloves.

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2015-03-09
Effective Date: 2018-03-09
Latest Revision Date: 2019-02-27
Expiry Date: 2021-03-08

Page: 1 of 1

...making excellence a habit.™

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9. Declaration of Conformity

MEDITECH GLOVES SDN BHD (580515-T)
Registration No. 200201012852

PT 3345, JALAN PERMATA 1/3,
ARAB MALAYSIAN INDUSTRIAL PARK,
71800 NILAI,
NEGERI SEMBILAN DARUL KHUSUS,
MALAYSIA
TEL: +6 06 799 7742
+6 06 799 7746
FAX: +6 06 799 7749
http: www.meditechgloves.com

MEDICAL DEVICE DIRECTIVE
EC DECLARATION OF CONFORMITY

Manufacturer/ Supplier :		**MEDITECH GLOVES SDN. BHD.** **PT 3345, Jalan Permata 1/3, Arab Malaysian Industrial Park, 71800 Nilai, Negeri Sembilan, Malaysia**
Authorised Representative:		**Best Putra Gloves (UK) Ltd., 103 Carrickasticken Road, Forkhill, Newry, County Down, BT35 9RL, Northern Ireland, United Kingdom.**
Model	:	**Polycare Latex Examination Gloves, Powder-free (MEPF3)**
Classification	:	**Class I**
Description	:	**Natural rubber latex examination gloves, powder-free & non-sterile. Ambidextrous gloves with beaded cuff, available in available in off-white to light yellow colours.**

Standards Applied:

EN 374-2:2014	**EN ISO 374-1:2016**	**EN 455-1:2020**	**EN 455-3:2015**
EN 374-4:2013	**EN 420:2003+A1:2009**	**EN 455-2:2015**	**EN 455-4:2009**

MEDITECH GLOVES SDN. BHD. declares that the device described above conforms to the relevant provision of **Directive 93/42/EEC,** and complies with the relevant Essential Requirements of the Annex V and is manufactured in accordance with the **ISO 13485: 2016** Medical Device Quality Management System (QMS).

Signed for and on behalf of the manufacturer, Meditech. Gloves. Sdn. Bhd.:

[redacted] 18/9/2020

DR. MOHAMMED EFFENDI MOHAMMED TENANG
Managing Director
Meditech Gloves Sdn. Bhd.

10. Manufacturing License

ASAL,
ORIGINAL

Borang IC/A 7 (Pin. 1/08)
Form IC/A 7 (Rev. 1/08)

KEMENTERIAN
PERDAGANGAN
ANTARABANGSA DAN
INDUSTRI MALAYSIA

MINISTRY OF
INTERNATIONAL TRADE
AND INDUSTRY OF
MALAYSIA

AKTA PENYELARASAN PERINDUSTRIAN, 1975
LESEN PENGILANGAN
INDUSTRIAL CO-ORDINATION ACT, 1975
MANUFACTURING LICENCE

No. Siri: A 030190
Serial No.:

No. Lesen: A 017184
Licence No.:

PADA MENURUT AKTA PENYELARASAN PERINDUSTRIAN, 1975
IN PURSUANCE OF THE INDUSTRIAL CO-ORDINATION ACT, 1975

Saya memberi lesen kepada.....
I license
MEDITECH GLOVES SDN. BHD.
(Nama pemohon/*Applicant's name*)

untuk bertindak sebagai PENGILANG BERLESEN mulai dari 23 April 2009
to act as LICENSED MANUFACTURER as from (Tarikh/*Date*)

di tempat pengilangan beralamat PT 3345, Jalan Permata 1/3, Arab Malaysian
at the place of manufacturing at
Industrial Park, 71800 Nilai, Negeri Sembilan Darul Khusus

bagi keluaran yang dinyatakan di bawah ini dan tertakluk kepada syarat yang dilampirkan bersama ini:
for product(s) specified hereunder and subject to the conditions attached herewith:

Keluaran:
Product:

'Surgical Gloves' dan 'Examination Gloves'

Bertarikh pada /i Ogos 2010
Dated this

[redacted]
PEGAWAI PELESEN
DATUK DR. REBECCA FATIMA STA MARIA
LICENSING OFFICER
Timbalan Ketua Setiausaha (Perdagangan)
Kementerian Perdagangan Antarabangsa & Industri
Malaysia

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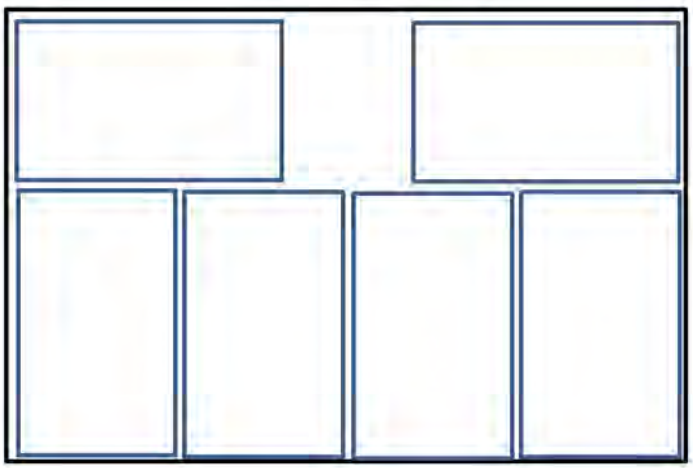
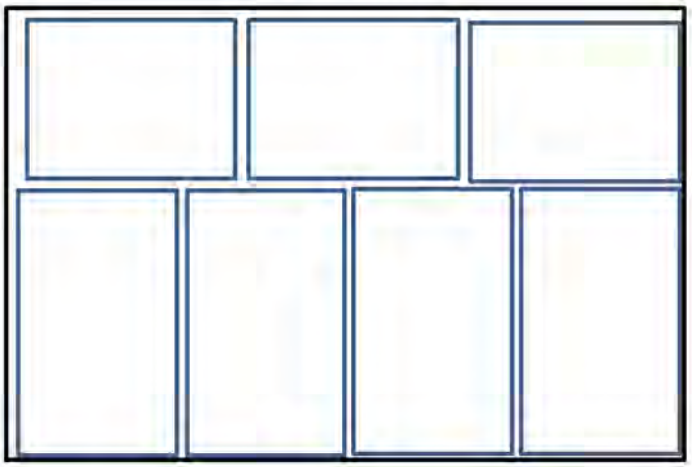
11. Carton on a Pallet Bird View

Surgical Carton on pallet bird view

Type A (Current Packing)



Type B (Suggest Packing)



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Exam Carton on pallet bird View

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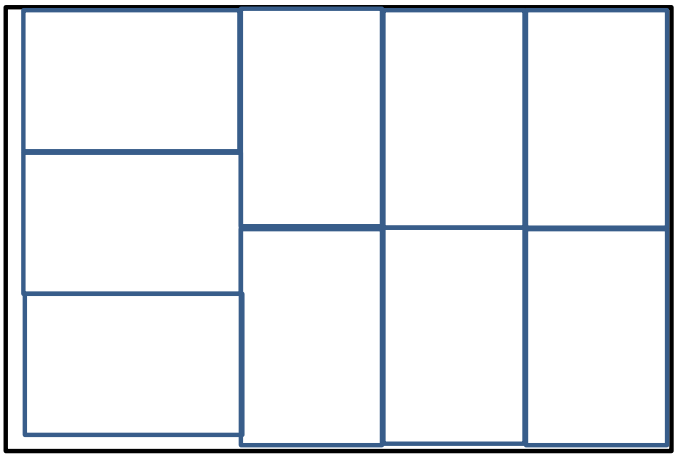

12. Image of Polycare Gloves

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13. Image of Box

↑Top

14. Image of Carton

↑Top

Príloha č. 2 - Návrh na plnenie kritérií

Identifikačné údaje:

Názov zákazky: „Výzva č. 3 – Jednorazové latexové rukavice“

Uchádzač: NAVAN s.r.o.,

Adresa sídla: Bániky 419/17, Pohronská Polhora 976 56

IČO: 45 453 951

Číslo účtu (IBAN): [redacted]

Telefónne číslo: [redacted]

E-mailová adresa: [redacted]@gmail.com

Ponuková cena v súlade s opisom predmetu zákazky:

Názov položky:	**Cena v eur bez DPH**	**Cena v eur s DPH**
Jednorazové latexové rukavice v množstve 120 000ks (veľkosť S)	**0,08**	**0,096**
Jednorazové latexové rukavice v množstve 90 000ks (veľkosť M)	**0,08**	**0,096**
Jednorazové latexové rukavice v množstve 110 000ks (veľkosť L)	**0,08**	**0,096**
Všetky ostatné služby (ako napr. dovoz, manipulácia, atď.)		
Cena spolu:	**25 600,-**	**30 720,-**

Platca/~~neplatca DPH~~ (nehodiace sa preškrtnite)

Čestné vyhlásenie: Predložením tejto ponuky zároveň **čestne vyhlasujem**, že postupujem v súlade s **etickým kódexom** uchádzača vydaným Úradom pre verejné obstarávanie:

https://www.uvo.gov.sk/zaujemcauchadzac/eticky-kodex-zaujemcu-uchadzaca-54b.html

V Pohronskej Polhore, dňa 07.06.2021

[redacted]6 56
2434

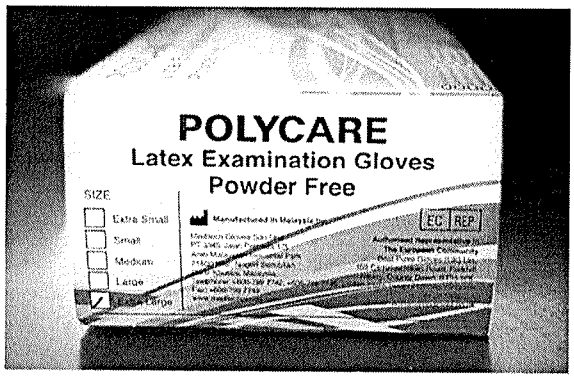
.....

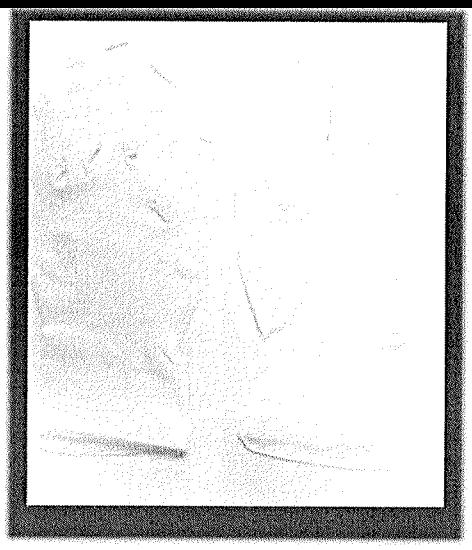
NAVAN s.r.o.

Ing. Marek TRNAVSKÝ, konateľ

Návod na použitie: Jednorazové vyšetrovacie a ochranné rukavice z prírodného kaučuku (NR), bez obsahu púdru, nesterilné.

[redacted]





[redacted]

Báníky 419/1
IČO:454539