Excellent Protection.
Excellent Performance.
Exceptional Value.

- CHEMOTHERAPY TESTED USING ASTM-D6978
- POWDER-FREE/LATEX FREE
- TEXTURED FINGERTIP
- 4 MIL
- HOSPITAL-GRADE MEDICAL EXAM GLOVE

WRP CareFit
Nitrile

www.carefitgloves.com

No Need to Compromise Comfort for Protection.

WRP CareFit Nitrile

WRP's Dermagrip Nitrile gloves deliver extraordinary protection, performance and value.

Made in Malaysia, the Dermagrip Chemotherapy Rated Examination Glove is distributed in the United States under the name CareFit.

Medical gloves provide protection from unwanted and dangerous substances for both healthcare professionals and patients. For over 10 years, Dermagrip/CareFit Chemotherapy Rated Examination Gloves have met and exceeded international product standards to provide uncompromising protection to its users.

Dermagrip/CareFit Chemotherapy Examination Gloves are formulated with 100% nitrile (Acrylonitrile-butadiene) providing an alternative solution for individuals who are allergic to natural rubber latex.

An optimized formulation and thickness make this gloves our softest and most comfortable nitrile gloves yet. 100% nitrile material eliminates Type 1 allergic reactions associated with natural rubber latex protein. Resists permeation by a wider range of chemical than natural rubber latex of the same thickness.

Dermagrip/CareFit Chemotherapy Glove Details

Product Information
Powder-free non-sterile

Primary Material
Acrylonitrile-butadiene

Thickness
Finger (at 15mm from the extreme tip) min .05mm
Palm (at center of palm) min .05mm
Cuff (at 25mm from cuff end) min .05mm

Powder
No powder lubricant added

Color
Blue (PMS 292U)

Design and Feature
Ambidextrous, textured surface at fingers and beaded cuff

Packing

X-Small	200 gloves per box	10 boxes per case
Small	200 gloves per box	10 boxes per case
Medium	200 gloves per box	10 boxes per case
Large	200 gloves per box	10 boxes per case
X-Large	180 gloves per box	10 boxes per case

Product Conformance
ASTM D6319
ASTM D6978
FDA 510(k)
Medical Device: in compliance with European Medical Device Directive 93/42/EEC (CE ClassI)
EN 455 Parts 1, 2, 3 and 4
Personal Protective Equipment of Complex Design Category III, in Compliance with 89/686/EEC, type tested to EN 420:2003+A12009
EN 374-2-2003, EN 374-3:2003 & EN 388:2003, CE 0086

Quality Assurance
US FDA Quality System Regulation (QSR)
ISO9001 Quality Management System
ISO13485 Quality Management System

No unpleasant odor

Powder free
To eliminate powder-induced
Irritation and dermatitis

Textured Finger Tips

100% nitrile
material eliminates Type I
allergic reactions
associated with natural
rubber latex protein

Meets or exceeds
EN455-2

Superior strength
And puncture resistance

An optimized
formulation and thickness
make CareFit Nitrile Exam
gloves the softest and
most comfortable
nitrile gloves yet.

Resists permeation by a
Wider range of
Chemical than natural
Rubber latex of the same
Thickness

Beaded cuff
Ensures easy
Donning and helps
Prevent roll down

PHOTOS/VIDEO


CareFit
Nitrile
MEDICAL GRADE
BLUE EXAMINATION GLOVES
S
200 Gloves
by Weight
POWDER-FREE
NON-STERILE
Manufactured by WRP Asia Pacific for 18 Supply
Tested For Use With Chemotherapy Drugs
In Accordance With ASTM D6978
CareFit
Nitrile
MEDICAL GRADE
BLUE EXAMINATION GLOVES
L
200 Gloves
by Weight
POWDER-FREE
NON-STERILE
Manufactured by WRP Asia Pacific for 18 Supply
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CareFit
Nitrile
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CareFit
Nitrile
MEDICAL GRADE
BLUE EXAMINATION GLOVES
XL
200 Gloves
by Weight
POWDER-FREE
NON-STERILE
Manufactured by WRP Asia Pacific for 18 Supply
Tested For Use With Chemotherapy Drugs
In Accordance With ASTM D6978


MEDICAL GRADE
BLUE EXAMINATION GLOVES
S
200 Gloves by Weight
Manufactured by WRP Asia Pacific
for 18 Supply Livingston, NJ 07039
www.18supply.com (973) 281-4446
CareFit
Nitrile
Not Made With
Natural Rubber Latex
Tested For Use With Chemotherapy Drugs
In Accordance With ASTM D6978
MEDICAL GRADE
BLUE EXAMINATION GLOVES
L
200 Gloves by Weight
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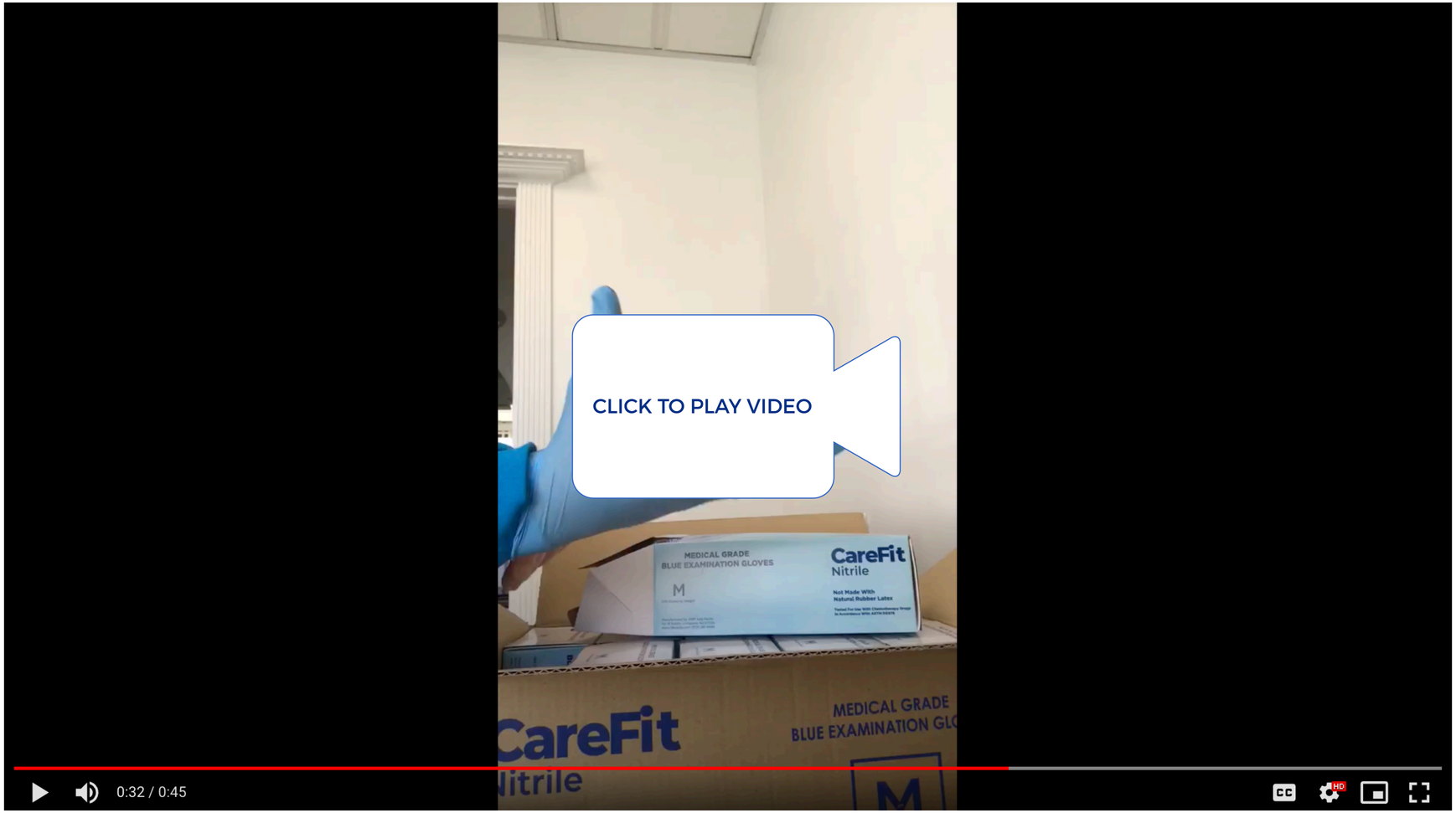
MEDICAL GRADE
BLUE EXAMINATION GLOVES
S
200 Gloves by Weight
MEDICAL GRADE
BLUE EXAMINATION GLOVES
L
200 Gloves by Weight
MEDICAL GRADE
BLUE EXAMINATION GLOVES
M
200 Gloves by Weight
MEDICAL GRADE
BLUE EXAMINATION GLOVES
XL
200 Gloves by Weight


MEDICAL GRADE
BLUE EXAMINATION GLOVES
Tested For Use With Chemotherapy Drugs In Accordance With ASTM D6978
Not Made With Natural Rubber Latex • Powder Free • Non Sterile
Size S, M, L and XL - 10 Dispenser X 200 Gloves = 2000 Gloves per Carton
M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MEDICAL GRADE
BLUE EXAMINATION GLOVES
M
CareFit
Nitrile
Not Made With
Natural Rubber Latex
0:32 / 0:45

FDA/REPORTS/CERTS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

February 5, 2015

WRP Asia Pacific Sdn Bhd
Ms. Sarala Devi Jayaraman
Regulatory Affairs Manager
Lot 1, Jalan 3, Kawasan Perusahaan
Bandar Baru Salak Tinggi
Sepang, Selangor Darul Ehsan
Malaysia 43900

Re: K141982
Trade/Device Name: Dermagrip Powder Free Blue Nitrile Patient Examination Gloves Tested for Use with Chemotherapy Drugs
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LZC, LZA
Dated: December 23, 2014
Received: December 29, 2014

Dear Ms. Jayaraman:

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 contact 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. 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,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital, Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K141982

Device Name
Dermagrip Powder Free Blue Nitrile Patient Examination Gloves, Non-Sterile, Tested for use with Chemotherapy Drugs

Indications for Use *(Describe)*

A 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.

These gloves were tested for use with Chemotherapy Drugs as per ASTM D6978-05 Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs:

Chemotherapy Drug Permeation
The following chemicals have been tested with these gloves.

Chemotherapy Drug	Concentration	Breakthrough Detection Time in Minutes
Flourouracil (Adrucil)	50.0mg/ml	> 240
Etopside (Toposar)	20.0mg/ml	> 240
Cyclophosphamide (Cytoxan)	20.0mg/ml	> 240
*Carmustine (BCNU)	3.3mg/ml	15.0
*Thiotepa	10.0mg/ml	2.0
Paclitaxel (Taxol)	6.0mg/ml	> 240
Doxorubicin Hydrochloride (Adriamycin)	2.0mg/ml	> 240
Dacarbazine	10.0mg/ml	> 240
Cisplatin	1.0mg/ml	> 240
Ifosfamide	50.0mg/ml	> 240
Mitoxantrone	2.0mg/ml	> 240
Vincristine Sulfate	1.0mg/ml	> 240

* Please note that the following drugs have extremely low permeation times:
Carmustine (BCNU) : 15 minutes and Thiotepa : 2 minutes

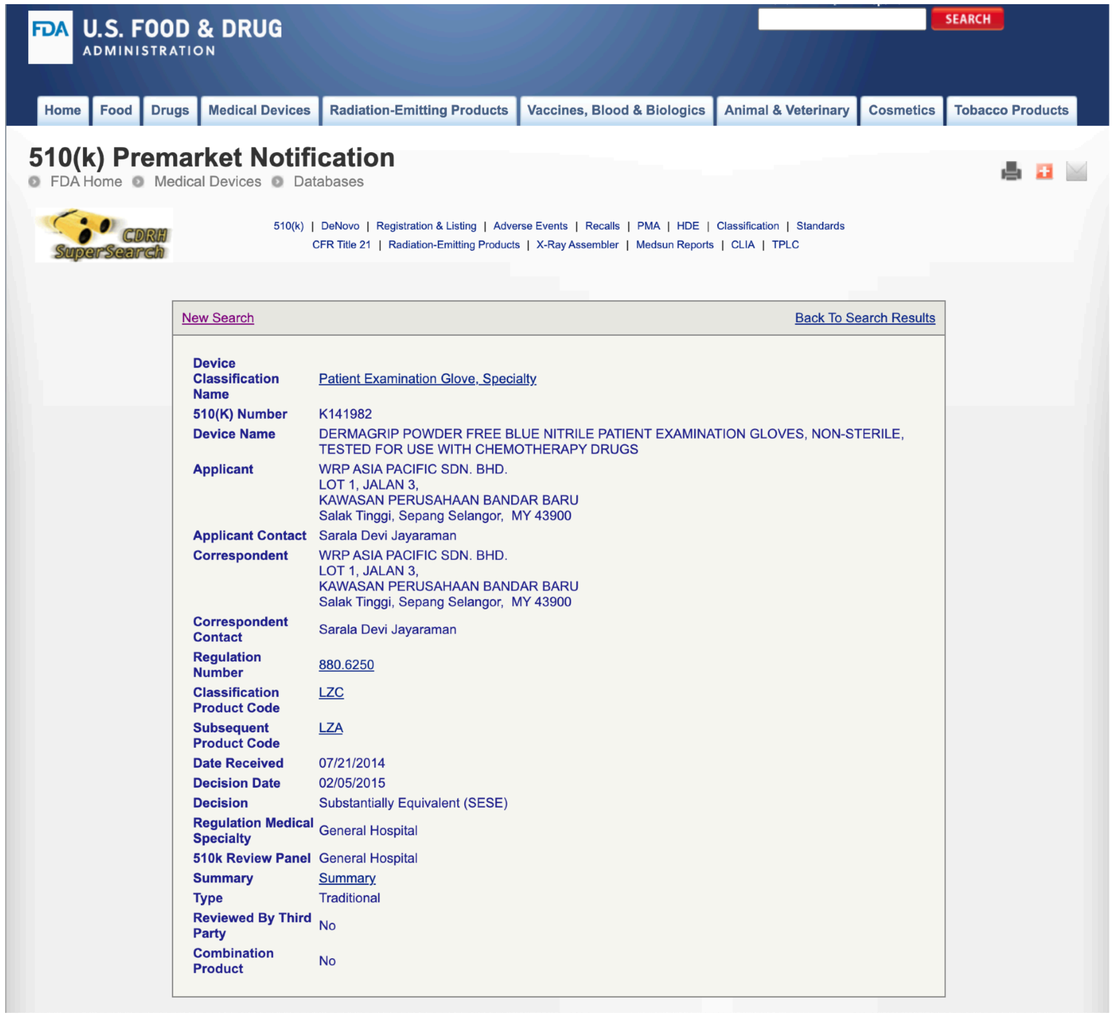
Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*



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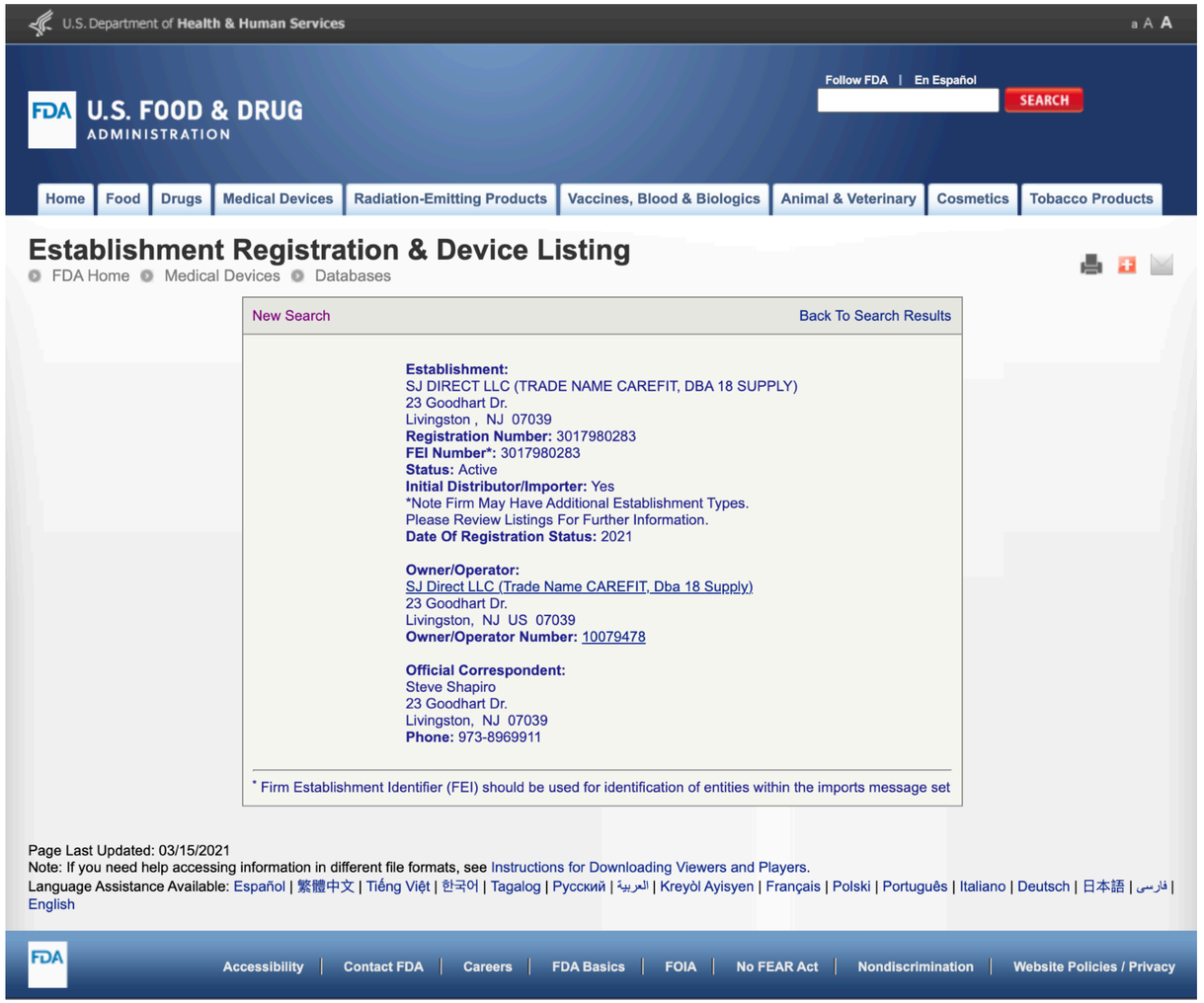
Device Classification Name	Patient Examination Glove, Specialty
510(K) Number	K141982
Device Name	DERMAGRIP POWDER FREE BLUE NITRILE PATIENT EXAMINATION GLOVES, NON-STERILE, TESTED FOR USE WITH CHEMOTHERAPY DRUGS
Applicant	WRP ASIA PACIFIC SDN. BHD. LOT 1, JALAN 3, KAWASAN PERUSAHAAN BANDAR BARU Salak Tinggi, Sepang Selangor, MY 43900
Applicant Contact	Sarala Devi Jayaraman
Correspondent	WRP ASIA PACIFIC SDN. BHD. LOT 1, JALAN 3, KAWASAN PERUSAHAAN BANDAR BARU Salak Tinggi, Sepang Selangor, MY 43900
Correspondent Contact	Sarala Devi Jayaraman
Regulation Number	880.6250
Classification Product Code	LZC
Subsequent Product Code	LZA
Date Received	07/21/2014
Decision Date	02/05/2015
Decision	Substantially Equivalent (SESE)
Regulation Medical Specialty	General Hospital
510k Review Panel	General Hospital
Summary	Summary
Type	Traditional
Reviewed By Third Party	No
Combination Product	No



U.S. Department of Health & Human Services

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Establishment Registration & Device Listing

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Establishment:
SJ DIRECT LLC (TRADE NAME CAREFIT, DBA 18 SUPPLY)
23 Goodhart Dr.
Livingston , NJ 07039
Registration Number: 3017980283
FEI Number*: 3017980283
Status: Active
Initial Distributor/Importer: Yes
*Note Firm May Have Additional Establishment Types.
Please Review Listings For Further Information.
Date Of Registration Status: 2021

Owner/Operator:
SJ Direct LLC (Trade Name CAREFIT, Dba 18 Supply)
23 Goodhart Dr.
Livingston, NJ US 07039
Owner/Operator Number: 10079478

Official Correspondent:
Steve Shapiro
23 Goodhart Dr.
Livingston, NJ 07039
Phone: 973-8969911

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

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Serial No.:

ASAL
ORIGINAL

PIHAK BERKUASA
PERANTI PERUBATAN

MEDICAL DEVICE AUTHORITY

PIHAK BERKUASA PERANTI PERUBATAN
MEDICAL DEVICE AUTHORITY
AKTA PERANTI PERUBATAN 2012 (AKTA 737)
MEDICAL DEVICE ACT 2012 (ACT 737)
LESEN ESTABLISMEN
ESTABLISHMENT LICENCE
Seksyen 24(1) Akta 737
Section 24(1) of Act 737

No. Lesen: **MDA-217-K12415**
Licence No.:

Tarikh Sah Lesen: **01/07/2018 - 30/06/2021**
Licence Validity Date:

Lesen adalah dengan ini diberi kepada:
Licence is hereby granted to:

WRP ASIA PACIFIC SDN. BHD.

yang beralamat di:
of
LOT 1, JALAN 3, KAWASAN PERUSAHAAN
BANDAR BARU SALAK TINGGI,
43900 SEPANG,
SELANGOR

Sebagai:
as
PEMBUAT
MANUFACTURER

Orang yang bertanggungjawab:
Person Responsible
DATO' LEE SON HONG (I/C NO. : 570226-08-5145)

Lesen ini diberikan tertakluk kepada peruntukan-peruntukan di bawah Akta 737 dan peraturan-peraturan dibawahnya serta syarat-syarat seperti di Lampiran 1.
This licence is granted subject to the provisions under Act 737 and its subsidiary legislations and the conditions as in Attachment 1.

ZAMANE BIN ABDUL RAHMAN
Ketua Eksekutif
Chief Executive
PIHAK BERKUASA PERANTI PERUBATAN
MEDICAL DEVICE AUTHORITY

Testing. Development. Problem Solving.

AKRON RUBBER DEVELOPMENT LABORATORY, INC.

June 13, 2014

· TEST REPORT ·

PN 114943

CHEMICAL ANALYTICAL SERVICES

Prepared For:
WRP Asia Pacific Sdn. Bhd.
Mr. Kirk Penner
Lot 1 Jalan 3 Kawasan
Perusahaan Bandar Baru
Salak Tinggi Sepang
Selangor Darul Ehsan 43900
Malaysia

Prepared By: _____
Tiffany L Heller
Assistant Manager, Pharmaceutical Services

Approved By: _____
Ana C Barbur, M.S.
Manager, Chemical, Microbiological & Pharmaceutical Services

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June 13, 2014

Mr. Kirk Penner
WRP Asia Pacific Sdn Bhd

Page 1 of 3 – PN 114943

Testing Date: May 5 – May 16, 2014

SUBJECT: Permeation testing per ASTM D 6978-05 on sample submitted by the above company.

RECEIVED: Glove samples identified as Dermagrip Powder Free Blue Nitrile Patient Examination Gloves, Non-sterile; Size Medium; Lot# 402011002.

TESTING CHEMOTHERAPY DRUGS:
Table 1. List of the Testing Chemotherapy Drugs, Sources, and Expiration Dates

TESTING CHEMOTHERAPY DRUGS	DRUG SOURCE
Carmustine (BCNU)	Bristol-Myers; Lot# 1C7008A; Expiration 05/2014
Cisplatin	USP; Lot# J0L420; Expiration 08/2014
Cyclophosphamide (Cytoxan)	Sigma Aldrich; Lot# SLBG4216V; Expiration 09/2014
Dacarbazine (DTIC)	APP; Lot# 6103390; Expiration 02/2015
Doxorubicin Hydrochloride	USP; Lot# L0K258; Expiration 06/2014
Etoposide (Toposar)	Teva; Lot# 31314884B; Expiration 02/2015
Fluorouracil	APP; Lot# 6106816; Expiration 02/2015
Ifosfamide	Phizer; Lot# 7800932; Expiration 02/2015
Mitoxantrone	USP; Lot# J0F278; Expiration 02/2015
Paclitaxel (Taxol)	APP; Lot# JD3004; Expiration 12/2014
Thiotepa	Sigma Aldrich; Lot# SLBD4239V; Expiration 10/2014
Vincristine Sulfate	Hospira; Lot# A037139AA; Expiration 02/2015

COLLECTION MEDIA:
The collection media, which were selected, are listed in Table 2.

Table 2. Collection Media for Testing Chemotherapy Drugs

TEST DRUG AND CONCENTRATION	COLLECTION MEDIUM
Carmustine (BCNU), 3.3 mg/ml (3,300 ppm)	10% Ethanol Aqueous Solution
Cisplatin, 1.0 mg/ml (1,000 ppm)	Distilled Water
Cyclophosphamide (Cytoxan), 20 mg/ml (20,000 ppm)	Distilled Water
Dacarbazine (DTIC), 10.0 mg/ml (10,000 ppm)	Distilled Water
Doxorubicin Hydrochloride, 2.0 mg/ml (2,000 ppm)	Distilled Water
Etoposide (Toposar), 20.0 mg/ml (20,000 ppm)	Distilled Water
Fluorouracil, 50.0 mg/ml (50,000 ppm)	9.20 pH Sodium Hydroxide Solution
Ifosfamide, 50.0 mg/ml (50,000 ppm)	Distilled Water
Mitoxantrone, 2.0mg/ml (2,000ppm)	Distilled Water
Paclitaxel (Taxol), 6.0 mg/ml (6,000 ppm)	30% Methanol Aqueous Solution
Thiotepa, 10.0 mg/ml (10,000 ppm)	Distilled Water
Vincristine Sulfate, 1.0 mg/ml (1,000 ppm)	Distilled Water

TESTING CONDITIONS:

Standard Test Method Used:	ASTM D 6978-05
Deviation From Standard Test Method:	Used 1" Permeation Cell
Analytical Method:	UV/VIS Spectrometry
Testing Temperature:	35.0°C ± 2.0
Collection System:	Closed Loop
Specimen Area Exposed:	5.067 cm2
Selected Data Points:	25/test
Number of Specimens Tested:	3/test
Location Sampled From:	Cuff area
Comments/Other Conditions:	Magnetic stir bar was used in the sampling chamber

DETECTION METHOD OF CHEMICAL PERMEATION; UV/VIS ABSORPTION SPECTROMETRY:
Instrument: Perkin Elmer UV/VIS Spectrometer Lambda 25
UV/VIS Absorption Spectrometry was used to measure the absorbance of test chemicals, which permeated through the specimens into the collection medium. The collection medium was circulated in a closed loop at 11 ml/minute of flow rate through the testing period. Data collection was performed according to the programmed schedule by means of UV Winlab software from the Perkin Elmer Corporation. The list of the characteristic wavelengths is shown below.

Table 3. Characteristic Wavelengths used in UV/VIS Absorption Spectrometry

TESTING CHEMOTHERAPY DRUGS	WAVELENGTH (nm)
Carmustine (BCNU), 3.3 mg/ml (3,300 ppm)	229
Cisplatin, 1.0 mg/ml (1,000 ppm)	199
Cyclophosphamide (Cytoxan), 20 mg/ml (20,000 ppm)	200
Dacarbazine (DTIC), 10.0 mg/ml (10,000 ppm)	320
Doxorubicin Hydrochloride, 2.0 mg/ml (2,000 ppm)	232
Etoposide (Toposar), 20.0 mg/ml (20,000 ppm)	205
Fluorouracil, 50.0 mg/ml (50,000 ppm)	269
Ifosfamide, 50.0 mg/ml (50,000 ppm)	200
Mitoxantrone, 2.0mg/ml (2,000ppm)	242
Paclitaxel (Taxol), 6.0 mg/ml (6,000 ppm)	231
Thiotepa, 10.0 mg/ml (10,000 ppm)	199
Vincristine Sulfate, 1.0 mg/ml (1,000 ppm)	220

SAMPLE CHARACTERISTICS:
Table 4. Thickness characteristics for the tested specimens: Dermagrip Powder Free Blue Nitrile Patient Examination Gloves, Non-sterile; Size Medium; Lot# 402011002.

Testing Chemotherapy Drugs	Thickness (mm)			Average (mm)	Weight/Unit Area (g/m2)
	Sample 1	Sample 2	Sample 3		
Carmustine (BCNU)	0.054	0.053	0.060	0.056	55.7
Cisplatin	0.054	0.054	0.060	0.056	
Cyclophosphamide (Cytoxan)	0.059	0.055	0.053	0.056	
Dacarbazine (DTIC)	0.058	0.053	0.054	0.055	
Doxorubicin Hydrochloride	0.061	0.057	0.056	0.058	
Etoposide (Toposar)	0.059	0.059	0.052	0.056	
Fluorouracil	0.054	0.056	0.055	0.055	
Ifosfamide	0.055	0.054	0.057	0.055	
Mitoxantrone	0.057	0.054	0.057	0.056	
Paclitaxel (Taxol)	0.055	0.056	0.058	0.056	
Thiotepa	0.060	0.052	0.062	0.058	
Vincristine Sulfate	0.063	0.057	0.063	0.061	

RESULTS:

Table 5. Permeation Test Results on: Dermagrip Powder Free Blue Nitrile Patient Examination Gloves, Non-sterile; Size Medium; Lot# 402011002.

TEST CHEMOTHERAPY DRUG AND CONCENTRATION	MINIMUM BREAKTHROUGH DETECTION TIME (Specimen 1/2/3) (Minutes)	STEADY STATE PERM. RATE (Specimen 1/2/3) ($\mu g/cm^2$/minute)	OTHER OBSERVATIONS
Carmustine (BCNU), 3.3 mg/ml (3,300 ppm)	15.0 (15.1,15.0,15.1)	0.9 (1.3,0.9,0.6)	Moderate swelling and no degradation
Cisplatin, 1.0 mg/ml (1,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Cyclophosphamide (Cytoxan), 20 mg/ml (20,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Dacarbazine (DTIC), 10.0 mg/ml (10,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Doxorubicin Hydrochloride, 2.0 mg/ml (2,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Etoposide (Toposar), 20.0 mg/ml (20,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Fluorouracil, 50.0 mg/ml (50,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Ifosfamide, 50.0 mg/ml (50,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Mitoxantrone, 2.0mg/ml (2,000ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Paclitaxel (Taxol), 6.0 mg/ml (6,000 ppm)	No breakthrough up to 240 min.	N/A	Moderate swelling and no degradation
Thiotepa, 10.0 mg/ml (10,000 ppm)	2.0 (7.2,2.0,4.4)	1.0 (0.8,1.0,1.3)	Slight swelling and no degradation
Vincristine Sulfate, 1.0 mg/ml (1,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation

Tiffany L. Heller
Assistant Manager
Pharmaceutical Services
AKRON RUBBER DEVELOPMENT LABORATORY, INC.

Ana C. Barbur, M.S,
Manager
Chemical, Microbiological and Pharmaceutical Services

bsi.

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 9001:2015

This is to certify that:

WRP Asia Pacific Sdn Bhd
Lot 1, Jalan 3
Kawasan Perusahaan
Bandar Baru Salak Tinggi
Sepang
Selangor
43900
Malaysia

Holds Certificate No: **FM 13934**

and operates a Quality Management System which complies with the requirements of ISO 9001:2015 for the following scope:

Design and manufacture of natural rubber and synthetic rubber sterile surgical gloves, sterile and non-sterile examination gloves and sterile urological balloon catheters.

For and on behalf of BSI:

Chris Cheung, Head of Compliance & Risk - Asia Pacific

Original Registration Date: 1991-12-03
Latest Revision Date: 2019-04-15

Effective Date: 2019-04-15
Expiry Date: 2021-12-20

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This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.
An electronic certificate can be authenticated online.
Printed copies can be validated at www.bsi-global.com/ClientDirectory or telephone +603 2242 4211.
Further clarifications regarding the scope of this certificate and the applicability of ISO 9001:2015 requirements may be obtained by consulting the organization.
This certificate is valid only if provided original copies are in complete set.

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A Member of the BSI Group of Companies.

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By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM – ISO 13485:2016

This is to certify that:

WRP Asia Pacific Sdn Bhd
Lot 1, Jalan 3
Kawasan Perusahaan
Bandar Baru Salak Tinggi
Sepang
Selangor
43900
Malaysia

DUNS Number: 89-417-8805

Holds certificate No: **MDSAP 691651**

Statement of Conformity: The company listed on this certificate has been audited to and found to conform with the following criteria: ISO 13485:2016 and Australia - Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure [if design controls are part of the certification]; Brasil - RDC ANVISA n. 16/2013, RDC ANVISA n. 23/2012, RDC ANVISA n. 67/2009; Canada - Medical Devices Regulations - Part 1- SOR 98/282; Japan - MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD Act; USA - 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 – Subparts A to D

The design and manufacture of natural rubber and synthetic rubber sterile surgical gloves, sterile and non-sterile examination gloves and sterile urological balloon catheters.

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk – Medical Devices

Original Registration Date: 2019-03-21 Effective Date: 2019-03-21 Expiry date: 2021-12-20

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BSI Group America Inc. is an MDSAP authorized auditing organization

This certificate remains the property of BSI and shall be returned immediately upon request.
To be read in conjunction with the scope above or the attached appendix.

Managed by: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA
A Member of the BSI Group of Companies.

Kitemark® Licence

No. KM 13936

BSI hereby grants to:

WRP Asia Pacific SDN BHD
Lot 1 Jalan 3
Kawasan Perusahaan Bandar Baru
Salak Tinggi
Sepang
Selangor
43900
Malaysia

In respect of:

BS EN 455 Parts 1, 2 & 3:2000

Medical gloves for single use

the right and Licence to use the Kitemark in accordance with the Kitemark Licence Conditions of Contract governing the use of the Kitemark, as may be updated from time to time by BSI, and as approved by the Registrar under the Trade Marks Act 1994 (the "Conditions"). All defined terms in this Licence shall have the same meaning as in the Conditions.

The use of the Kitemark is authorized in respect of the Product(s) detailed on this Licence provided at or from the above address.

For and on behalf of BSI:

Alastair Trivett, Managing Director, BSI Product Services – Global

First granted: **3 Dec 1991** Date: **20 Jul 2007** Page: 1 of 2

UKAS PRODUCT CERTIFICATION
003

The licence remains the property of BSI and shall be returned immediately upon request. This licence does not expire. To check its validity telephone: +44 (0)1442 230442
BSI is incorporated by Royal Charter

BSI Product Services

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PS027/0806/EP