



**U.S. FOOD & DRUG
ADMINISTRATION**

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Certificate No. 10469-6-2023

CERTIFICATE TO FOREIGN GOVERNMENT

In order to allow the importation of United States products into foreign countries, the U.S. Food and Drug Administration (FDA) certifies the following information concerning the product(s) to be exported listed below:

Name of Product(s)

See Attached List

(Eight Pages)

Name of Manufacturer/Distributor, Address

See Attached List

(Two Pages)

The product(s) described above (and the manufacturing/distribution site(s) which produces/distributes it) is subject to the jurisdiction of the FDA under the Federal Food, Drug, and Cosmetic Act.

It is certified that the above product(s) may be marketed in, and legally exported from, the United States of America at this time. The manufacturing plant(s) in which the product(s) is produced is subject to periodic inspections.

Sincerely,

CDR Cesar A. Perez, PhD, Director
DRP2: Division of Establishment Support
Office of Regulatory Programs
Office of Product Evaluation and Quality
Center for Devices and Radiological Health
U.S. Food and Drug Administration, DHHS

This certificate is valid from June 14, 2023 to June 13, 2025.





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Certificate to Foreign Government - Name of Manufacturer/Distributor Attachment Page 1 of 2

Name of Manufacturer

Legal Manufacturer

HOLLISTER INCORPORATED
2000 HOLLISTER DR.
LIBERTYVILLE, IL
USA 60048

Contract Manufacturer

ACUPAC PACKAGING, INC.
55 Ramapo Valley Rd
MAHWAH, NJ
USA 07430

Contract Manufacturer

Advanced Medical Solutions Ltd
Premier Park, 33 Road One
WINSFORD INDUSTRIAL ESTATE
WINSFORD, Cheshire East
UNITED KINGDOM CW7 3RT

Contract Manufacturer

ANDERSONBRECON INC.
1129 18th Ave
ROCKFORD, IL
USA 61104

Contract Manufacturer

AURENA LABORATORIES AB
Fjarrviksvagen 22
Karlstad, Varmland
SWEDEN 65350

Manufacturer

HOLLISTER ULC
FOXFORD RD.
REHINS BALLINA, Mayo
IRELAND

Manufacturer

Hollister Medical India Private Limited
Plot No. 27, Sector 5
Phase II, HSIIDC Growth Center
Bawal, Rewari, Haryana
INDIA 123501

Contract Manufacturer

BIOMED LABORATORIES, LLC
8181 Eastpoint Dr Ste 500
Dallas, TX
USA 75227

Contract Manufacturer

DAVOL SURGICAL INNOVATIONS
AVE. ROBERTO FIERRO No. 6408
PARQUE IND. AEROPUERTO
CD. JUAREZ, Chihuahua
MEXICO

Contract Manufacturer

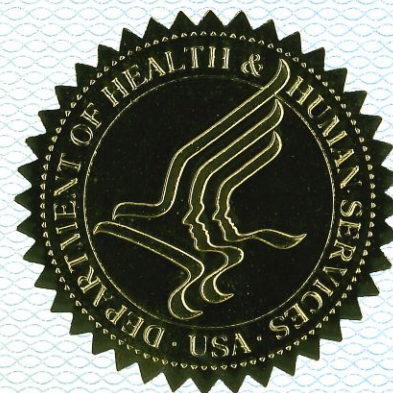
EUROMED, INC.
25 Corporate Dr
ORANGEBURG, NY
USA 10962

Contract Manufacturer

HUIDA BIOPHARMACEUTICALS (SUZHOU) LTD
8 Weipu Rd
SUZHOU INDUSTRIAL PARK
SUZHOU, Jiangsu
CHINA 215127

Manufacturer

Hollister Lietuva UAB
Oro parko str. 2, Sergeicikai village
Kaunas district, Kaunas
LITHUANIA LT-54462





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Manufacturer

HOLLISTER INCORPORATED
1502 E Laharpe St
KIRKSVILLE, MO
USA 63501

Contract Manufacturer

SEI Medical S.A. de C.V.
ROBERTO FIERRO #6420 & FRANCISCO SARABIA
PARQUE INDUSTRIAL AEROPUERTO
Juarez, Chihuahua
MEXICO 32685

Contract Manufacturer

Scapa Tapes North America, LLC
2565 Bertelkamp Lane
Knoxville, TN
USA 37931

Manufacturer

HOLLISTER INCORPORATED
366 Draft Ave
STUARTS DRAFT, VA
USA 24477

----END OF MANUFACTURER/DISTRIBUTOR LIST----





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Name of Manufacturer

Contract Manufacturer

ACUPAC PACKAGING, INC.

55 Ramapo Valley Rd

MAHWAH, NJ

USA 07430

Name of Product(s)

~Ostomy~

Adapt Adhesive Remover Wipe-7760

Name of Manufacturer

Contract Manufacturer

Advanced Medical Solutions Ltd

Premier Park, 33 Road One

WINSFORD INDUSTRIAL ESTATE

WINSFORD, Cheshire East

UNITED KINGDOM CW7 3RT

Name of Product(s)

~Wound Care~

Restore CalciCare Calcium Alginate Dressing-9937

Restore CalciCare Calcium Alginate Dressing-9939

Restore CalciCare Calcium Alginate Dressing-9940

Name of Manufacturer

Contract Manufacturer

ANDERSONBRECON INC.

1129 18th Ave

ROCKFORD, IL

USA 61104

Name of Product(s)

~Ostomy~

Adapt Ostomy Pouch Lubricating Deodorant-78501

Name of Manufacturer

Contract Manufacturer

AURENA LABORATORIES AB

Fjarrviksvagen 22

Karlstad, Varmland

SWEDEN 65350

Name of Product(s)

~Ostomy~

Adapt Medical Adhesive Remover-7737

Name of Manufacturer

Manufacturer

HOLLISTER ULC

FOXFORD RD.

REHINS BALLINA, Mayo

IRELAND

Name of Product(s)

~Ostomy~

Compact 1-Piece Urostomy Pouch-1401

Compact Closed Pouch-3460





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New Image 2-Piece Drainable Ostomy Pouch-18292
Pouchkins 1-Piece Pediatric Drainable Ostomy Pouch-3795
Premier 1-Piece Drainable Ostomy Pouch-88302
Premier 1-Piece Drainable Ostomy Pouch-88402
~Continence Care~
VaPro No Touch Urethral Intermittent Catheter-73124
VaPro No Touch Urethral Intermittent Catheter-73144
VaPro No Touch Urethral Intermittent Catheter-73164
VaPro No Touch Urethral Intermittent Catheter-72082
VaPro No Touch Urethral Intermittent Catheter-72084
VaPro No Touch Urethral Intermittent Catheter-72102
VaPro No Touch Urethral Intermittent Catheter-72104
VaPro No Touch Urethral Intermittent Catheter-72122
VaPro No Touch Urethral Intermittent Catheter-72124
VaPro No Touch Urethral Intermittent Catheter-72144
VaPro No Touch Urethral Intermittent Catheter-72164
VaPro No Touch Urethral Intermittent Catheter-70104
VaPro No Touch Urethral Intermittent Catheter-70124
VaPro No Touch Urethral Intermittent Catheter-70144
VaPro No Touch Urethral Intermittent Catheter-70164

Name of Manufacturer

Manufacturer

Hollister Medical India Private Limited
Plot No. 27, Sector 5
Phase II, HSIIDC Growth Center
Bawal, Rewari, Haryana
INDIA 123501

Name of Product(s)

~Continence Care~
Hollister Leg Bag Straps-9343
Hollister Extension Tubing with Connector-9345
Hollister Urinary Leg Bag-9805
Hollister Urinary Leg Bag-9814
Hollister Urinary Leg Bag Combination Pack-9349
InstantCath Pre-lubricated Urethral Intermittent Catheter-9670
InstantCath Pre-lubricated Urethral Intermittent Catheter-9671
InstantCath Pre-lubricated Urethral Intermittent Catheter-9672
InstantCath Pre-lubricated Urethral Intermittent Catheter-9673
InstantCath Pre-lubricated Urethral Intermittent Catheter-9674
InstantCath Pre-lubricated Urethral Intermittent Catheter-9675
InstantCath Pre-lubricated Urethral Intermittent Catheter-9676
InstantCath Pre-lubricated Urethral Intermittent Catheter-9677
InstantCath Pre-lubricated Urethral Intermittent Catheter-9678
~Ostomy~
Hollister Ostomy Irrigator Sleeve-7724
Hollister Stoma Cone Irrigator Kit-7718

Name of Manufacturer

Contract Manufacturer

BIOMED LABORATORIES, LLC
8181 Eastpoint Dr Ste 500
Dallas, TX
USA 75227

Name of Product(s)

~Ostomy~





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Adapt Stoma Powder-7906

Name of Manufacturer

Contract Manufacturer

DAVOL SURGICAL INNOVATIONS
AVE. ROBERTO FIERRO No. 6408
PARQUE IND. AEROPUERTO
CD. JUAREZ, Chihuahua
MEXICO

Name of Product(s)

~Continence Care~

InView Standard Male Incontinence Sheath Self-Adhesive-97225
InView Standard Male Incontinence Sheath Self-Adhesive-97229
InView Standard Male Incontinence Sheath Self-Adhesive-97232
InView Standard Male Incontinence Sheath Self-Adhesive-97236
InView Standard Male Incontinence Sheath Self-Adhesive-97241

Name of Manufacturer

Contract Manufacturer

EUROMED, INC.
25 Corporate Dr
ORANGEBURG, NY
USA 10962

Name of Product(s)

~Ostomy~

CeraPlus Barrier Extenders-79402

Name of Manufacturer

Contract Manufacturer

HUIDA BIOPHARMACEUTICALS (SUZHOU) LTD
8 Weipu Rd
SUZHOU INDUSTRIAL PARK
SUZHOU, Jiangsu
CHINA 215127

Name of Product(s)

~Ostomy~

Adapt Skin Protective Wipes-7917

Name of Manufacturer

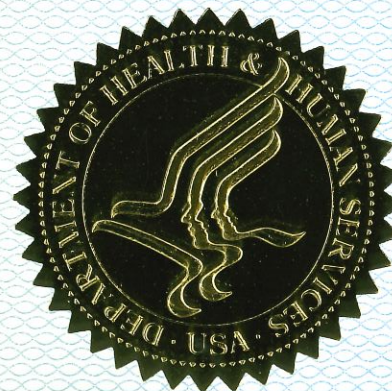
Manufacturer

Hollister Lietuva UAB
Oro parko str. 2, Sergeicikai village
Kaunas district, Kaunas
LITHUANIA LT-54462

Name of Product(s)

~Ostomy~

New Image 2-Piece Drainable Ostomy Pouch-18102
New Image 2-Piece Drainable Ostomy Pouch-18103
New Image 2-Piece Drainable Ostomy Pouch-18104
New Image 2-Piece Drainable Ostomy Pouch-18122
New Image 2-Piece Drainable Ostomy Pouch-18123
New Image 2-Piece Drainable Ostomy Pouch-18124
New Image 2-Piece Ostomy Skin Barrier-14202
New Image 2-Piece Ostomy Skin Barrier-14203





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New Image 2-Piece Ostomy Skin Barrier-14204
Premier 1-Piece Closed Ostomy Pouch-82300
Premier 1-Piece Closed Ostomy Pouch-82302
Premier 1-Piece Closed Ostomy Pouch-82402
Suavita 1-Piece Drainable Pouch-7610
Suavita 1-Piece Drainable Pouch-7620
Suavita 2-Piece Drainable Pouch-45603
Suavita 2-Piece Drainable Pouch-45604
Suavita 2-Piece Drainable Pouch-45703
Suavita 2-Piece Drainable Pouch-45704
Suavita 2-Piece Drainable Pouch-47603
Suavita 2-Piece Drainable Pouch-47604
Suavita 2-Piece Drainable Pouch-47703
Suavita 2-Piece Drainable Pouch-47704
Suavita 2-Piece Skin Barrier-45541
Suavita 2-Piece Skin Barrier-47541

Name of Manufacturer

Manufacturer

HOLLISTER INCORPORATED
1502 E Laharpe St
KIRKSVILLE, MO
USA 63501

Name of Product(s)

~Ostomy~

Hollister Ostomy Pouch Clamp-8770-200
Hollister Ostomy Pouch Clamp-8770
Hollister Urostomy Drain Tube Adapter-7331
Loop Ostomy Bridge-7767
Pouchkins Newborn Ostomy Pouch-3778
Pouchkins Premie Ostomy Pouch-3777

Name of Manufacturer

Contract Manufacturer

Scapa Tapes North America, LLC
2565 Bertelkamp Lane
Knoxville, TN
USA 37931

Name of Product(s)

~Ostomy~

Karaya 5 Stoma Powder-7905

Name of Manufacturer

Contract Manufacturer

SEI Medical S.A. de C.V.
ROBERTO FIERRO #6420 & FRANCISCO SARABIA
PARQUE INDUSTRIAL AEROPUERTO
Juarez, Chihuahua
MEXICO 32685

Name of Product(s)

~Ostomy~

Adapt Ostomy Belt-7299
Adapt Ostomy Belt-7300
~Critical Care~
Hollister Feeding Tube Attachment Device-9786





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Name of Manufacturer

Manufacturer

HOLLISTER INCORPORATED
366 Draft Ave
STUARTS DRAFT, VA
USA 24477

Name of Product(s)

~Ostomy~

Adapt CeraRing Ostomy Barrier Ring-8805
Adapt CeraRing Ostomy Barrier Ring-8815
Adapt Ostomy Barrier Ring-7805
Adapt Ostomy Barrier Ring-7806
Adapt Ostomy Barrier Ring-79520
Adapt Ostomy Barrier Ring-79530
Adapt Ostomy Barrier Ring-79540
Adapt Ostomy Barrier Ring-79601
Adapt Ostomy Barrier Ring-79602
Adapt Ostomy Barrier Ring-79603
Adapt Ostomy Skin Barrier Strips-79400
Adapt Ostomy Paste-79300
Adapt Ostomy Paste-79301
Adapt Ostomy Pouch Lubricating Deodorant-78500
Compact 1-Piece Drainable Ostomy Pouch-3250
Hollister Ostomy Stoma Cap-3184
Hollister Ostomy Pouch Replacement Filters-7766
Hollister Wound Drainage Collector with Skin Barrier-9773
Hollister Wound Drainage Collector with Skin Barrier-9776
Hollister Wound Drainage Collector with Skin Barrier-9778
Karaya 5 1-Piece Closed Ostomy Pouch-3323
Karaya 5 1-Piece Closed Ostomy Pouch-3324
Karaya 5 1-Piece Closed Ostomy Pouch-3325
Karaya 5 1-Piece Closed Ostomy Pouch-3326
Karaya 5 1-Piece Closed Ostomy Pouch-3328
Karaya 5 1-Piece Closed Ostomy Pouch-3329
Karaya 5 1-Piece Closed Ostomy Pouch-7164
Karaya 5 1-Piece Closed Ostomy Pouch-7165
Karaya 5 1-Piece Drainable Ostomy Pouch-3222
Karaya 5 1-Piece Drainable Ostomy Pouch-3223
Karaya 5 1-Piece Drainable Ostomy Pouch-3224
Karaya 5 1-Piece Drainable Ostomy Pouch-3225
Karaya 5 1-Piece Drainable Ostomy Pouch-3228
Karaya 5 1-Piece Drainable Ostomy Pouch-3229
Karaya 5 1-Piece Drainable Ostomy Pouch-3273
Karaya 5 1-Piece Drainable Ostomy Pouch-3274
Karaya 5 1-Piece Drainable Ostomy Pouch-3725
Karaya 5 1-Piece Drainable Ostomy Pouch-3726
Karaya 5 1-Piece Drainable Ostomy Pouch-3728
Karaya 5 1-Piece Urostomy Pouch-1433
Karaya 5 1-Piece Urostomy Pouch-1434
Karaya 5 1-Piece Urostomy Pouch-1438
Karaya 5 Ostomy Paste-7910
New Image 2-Piece Closed Ostomy Pouch-18372-30
New Image 2-Piece Closed Ostomy Pouch-18373-30
New Image 2-Piece Closed Ostomy Pouch-18374-30
New Image 2-Piece Closed Ostomy Pouch-18372
New Image 2-Piece Closed Ostomy Pouch-18373





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New Image 2-Piece Closed Ostomy Pouch-18374
New Image 2-Piece Drainable Ostomy Pouch-18006
New Image 2-Piece Drainable Ostomy Pouch-18102
New Image 2-Piece Drainable Ostomy Pouch-18103
New Image 2-Piece Drainable Ostomy Pouch-18104
New Image 2-Piece Drainable Ostomy Pouch-18112
New Image 2-Piece Drainable Ostomy Pouch-18113
New Image 2-Piece Drainable Ostomy Pouch-18114
New Image 2-Piece Drainable Ostomy Pouch-18122
New Image 2-Piece Drainable Ostomy Pouch-18123
New Image 2-Piece Drainable Ostomy Pouch-18124
New Image 2-Piece Drainable Ostomy Pouch-18132
New Image 2-Piece Drainable Ostomy Pouch-18133
New Image 2-Piece Drainable Ostomy Pouch-18134
New Image 2-Piece Drainable Ostomy Pouch-18176
New Image 2-Piece Drainable Ostomy Pouch-18182
New Image 2-Piece Drainable Ostomy Pouch-18183
New Image 2-Piece Drainable Ostomy Pouch-18184
New Image 2-Piece Drainable Ostomy Pouch-18192
New Image 2-Piece Drainable Ostomy Pouch-18193
New Image 2-Piece Drainable Ostomy Pouch-18194
New Image 2-Piece Drainable Ostomy Pouch-18202
New Image 2-Piece Drainable Ostomy Pouch-18203
New Image 2-Piece Drainable Ostomy Pouch-18204
New Image 2-Piece Ostomy Skin Barrier-11202
New Image 2-Piece Ostomy Skin Barrier-11203
New Image 2-Piece Ostomy Skin Barrier-11204
New Image 2-Piece Ostomy Skin Barrier-11402
New Image 2-Piece Ostomy Skin Barrier-11403
New Image 2-Piece Ostomy Skin Barrier-11404
New Image 2-Piece Ostomy Skin Barrier-13402
New Image 2-Piece Ostomy Skin Barrier-13403
New Image 2-Piece Ostomy Skin Barrier-13404
New Image 2-Piece Ostomy Skin Barrier-13503
New Image 2-Piece Ostomy Skin Barrier-13504
New Image 2-Piece Ostomy Skin Barrier-13505
New Image 2-Piece Ostomy Skin Barrier-13506
New Image 2-Piece Ostomy Skin Barrier-13802
New Image 2-Piece Ostomy Skin Barrier-13803
New Image 2-Piece Ostomy Skin Barrier-13804
New Image 2-Piece Ostomy Skin Barrier-13901
New Image 2-Piece Ostomy Skin Barrier-13902
New Image 2-Piece Ostomy Skin Barrier-13903
New Image 2-Piece Ostomy Skin Barrier-13904
New Image 2-Piece Ostomy Skin Barrier-13905
New Image 2-Piece Ostomy Skin Barrier-13906
New Image 2-Piece Ostomy Skin Barrier-13907
New Image 2-Piece Ostomy Skin Barrier-13908
New Image 2-Piece Ostomy Skin Barrier-13910
New Image 2-Piece Ostomy Skin Barrier-13911
New Image 2-Piece Ostomy Skin Barrier-14206
New Image 2-Piece Ostomy Skin Barrier-14602
New Image 2-Piece Ostomy Skin Barrier-14603
New Image 2-Piece Ostomy Skin Barrier-14604
New Image 2-Piece Ostomy Skin Barrier-14606
New Image 2-Piece Ostomy Skin Barrier-14802
New Image 2-Piece Ostomy Skin Barrier-14803
New Image 2-Piece Ostomy Skin Barrier-14804





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New Image 2-Piece Ostomy Skin Barrier-15102
New Image 2-Piece Ostomy Skin Barrier-15103
New Image 2-Piece Ostomy Skin Barrier-15104
New Image 2-Piece Ostomy Skin Barrier-15302
New Image 2-Piece Ostomy Skin Barrier-15303
New Image 2-Piece Ostomy Skin Barrier-15304
New Image 2-Piece Ostomy Skin Barrier-15602
New Image 2-Piece Ostomy Skin Barrier-15603
New Image 2-Piece Ostomy Skin Barrier-15604
New Image 2-Piece Ostomy Skin Barrier-15802
New Image 2-Piece Ostomy Skin Barrier-15803
New Image 2-Piece Ostomy Skin Barrier-15804
New Image 2-Piece Urostomy Pouch-18402
New Image 2-Piece Urostomy Pouch-18403
New Image 2-Piece Urostomy Pouch-18404
New Image 2-Piece Urostomy Pouch-18422
New Image 2-Piece Urostomy Pouch-18423
New Image 2-Piece Urostomy Pouch-18424
New Image 2-Piece Urostomy Pouch-18912
Pouchkins 1-Piece Pediatric Drainable Ostomy Pouch-3796
Pouchkins 1-Piece Pediatric Urostomy Pouch-3797
Pouchkins 2-Piece Pediatric Drainable Ostomy Pouch-3799
Pouchkins 2-Piece Pediatric Ostomy Skin Barrier-3761
Premier 1-Piece Drainable Ostomy Pouch-8331
Premier 1-Piece Drainable Ostomy Pouch-8510
Premier 1-Piece Drainable Ostomy Pouch-8511
Premier 1-Piece Drainable Ostomy Pouch-8512
Premier 1-Piece Drainable Ostomy Pouch-8513
Premier 1-Piece Drainable Ostomy Pouch-8514
Premier 1-Piece Drainable Ostomy Pouch-8515
Premier 1-Piece Drainable Ostomy Pouch-8531
Premier 1-Piece Drainable Ostomy Pouch-8551
Premier 1-Piece Drainable Ostomy Pouch-8592
Premier 1-Piece Drainable Ostomy Pouch-8593
Premier 1-Piece Drainable Ostomy Pouch-8594
Premier 1-Piece Drainable Ostomy Pouch-8611
Premier 1-Piece Drainable Ostomy Pouch-8612
Premier 1-Piece Drainable Ostomy Pouch-8613
Premier 1-Piece Drainable Ostomy Pouch-8614
Premier 1-Piece Drainable Ostomy Pouch-8615
Premier 1-Piece Drainable Ostomy Pouch-8616
Premier 1-Piece Drainable Ostomy Pouch-8617
Premier 1-Piece Drainable Ostomy Pouch-8618
Premier 1-Piece Drainable Ostomy Pouch-8619
Premier 1-Piece Drainable Ostomy Pouch-8631
Premier 1-Piece Drainable Ostomy Pouch-85011
Premier 1-Piece Drainable Ostomy Pouch-85118
Premier 1-Piece Drainable Ostomy Pouch-85119
Premier 1-Piece Drainable Ostomy Pouch-85211
Premier 1-Piece Drainable Ostomy Pouch-88300
Premier 1-Piece Drainable Ostomy Pouch-88400
Premier 1-Piece Drainable Ostomy Pouch with Soft Tap-80110
Premier 1-Piece Drainable Ostomy Pouch with Soft Tap-80070
Premier 1-Piece Urostomy Pouch-8460
Premium Ostomy Skin Barrier-7900
Premium Ostomy Skin Barrier-7901
~Critical Care~
AnchorFast Oral Endotracheal Tube Fastener-9799





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AnchorFast Oral Endotracheal Tube Fastener Straps-9788

Hollister Drainable Fecal Collector-9821

Hollister Drainable Fecal Collector-9822

Horizontal Drain/Tube Attachment Device-9781

Vertical Drain/Tube Attachment Device-9782

AnchorFast Guard Endotracheal Tube Fastener-9800

AnchorFast SlimFit Oral Endotracheal Tube Fastener-9787

~Wound Care~

Restore Cx Hydrocolloid Dressing-9933

Restore Cx Hydrocolloid Dressing-9936

Restore Extra Thin Wound Care Dressing-9921

Restore Extra Thin Wound Care Dressing-9923

Restore Extra Thin Wound Care Dressing-9925

Restore Hydrocolloid Dressing-9930

Restore Hydrocolloid Dressing-9935

Restore Plus Hydrocolloid Dressing-9953

Restore Plus Hydrocolloid Dressing-9955

Restore Plus Hydrocolloid Dressing-9956

Restore Plus Hydrocolloid Dressing-9958

Restore Plus Hydrocolloid Dressing-9965

-----END OF PRODUCT LIST-----

