

Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993

Certificate No. 5888-9-2009

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
(15 Pages)

Name of Manufacturer/Distributor Address

Legal Manufacturer:

Kendall, a division of Tyco Healthcare Group LP
15 Hampshire Street
Mansfield, MA 02048

Manufacturing Facility:

Kendall, a Division of Tyco Healthcare Group LP
5439 State Route 40
Argyle, NY 12809

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. The last such inspection showed that the plant(s), at that time, appeared to be in substantial compliance with current good manufacturing practice requirements for the products(s) listed above.

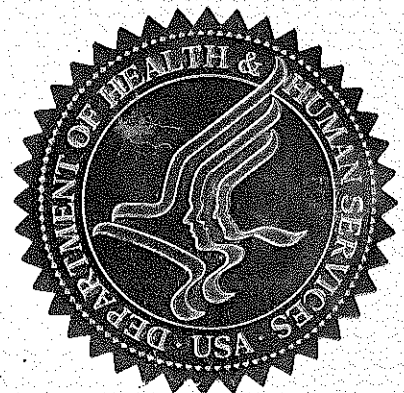
Theresa McDonald
Chief, Regulatory Policy and Systems Branch
Division of Risk Management Operations
Office of Compliance
Center for Devices and Radiological Health

This certificate expires 24 months from the date notarized.

COUNTY OF MONTGOMERY
STATE OF MARYLAND

Subscribed and sworn to before me this 28 day of Sept month 2009 year.

CATHRYN N. MORRIS
NOTARY PUBLIC STATE OF MARYLAND
County of Montgomery
My Commission Expires January 4, 2013



Control de Alimentos y Medicamentos
9200 Corporate Boulevard
Rockville, Maryland 20850

Certificado No. 5888-9-2009

CERTIFICADO EXPEDIDO A UN GOBIERNO EXTRANJERO

Con el fin de permitir la importación de productos de los Estados Unidos a otros países, la División de Control de Medicamentos y Alimentos (FDA) de los EE.UU. certifica la siguiente información con respecto a los productos a ser exportados, los cuales se relacionan a continuación:

<u>Nombre del Producto</u>	<u>Nombre del Fabricante/Dirección del Distribuidor</u>
----------------------------	---

Ver listado en el anexo

Distribuidor
Kendall, a Division de Tyco Healthcare Group LP
15 Hampshire Street
Mansfield, MA 02048

Fabricante:
Kendall, a Division de Tyco Healthcare Group LP
5439 State Route 40
Argely, NY 12809

Los productos descritos anteriormente al igual que la planta de fabricación o distribución donde se producen o distribuyen están sujetos a la jurisdicción de la FDA de conformidad con el Decreto Federal sobre Alimentos, Medicamentos y Cosméticos.

Se certifica que, actualmente, los productos arriba mencionados pueden ser comercializados y exportados legalmente desde los Estados Unidos de Norteamérica. La planta de fabricación en la cual se elaboran los productos es sometida a inspecciones periódicas. En la última inspección realizada se determinó que la planta cumplía sustancialmente con los requisitos de las Buenas Prácticas de Manufactura actuales (cGMP) para los productos en cuestión.

Firma
Theresa Mc Donald
Jefe de la Unidad de Políticas Regulatorias y Sistemas
División de Operaciones para el Manejo del Riesgo
Oficina de Cumplimiento
Centro para la Evaluación de Equipos y Salud Radiológica

(Este certificado caduca en 24 meses a partir de la fecha de autenticación)

CONDADO DE MONTGOMERY, ESTADO DE MARYLAND

Suscrito y jurado ante mí a los veintiún (28) días del mes de septiembre de 2009

(firma), Cathryn W. Morris Notaria Pública

Firma y sello registrados ante el Ministerio de Relaciones Exteriores y
la Embajada de los E.E.U.U. en Santa Fe de Bogotá.

APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. Country: *United States of America*

This public document

2. has been signed by *Theresa McDonald*

3. acting in the capacity of *Chief, Regulatory Policy and Systems Branch*

4. bears the seal/stamp of *U.S. Department of Health and Human Services*

Certified

5. at Washington, D.C.

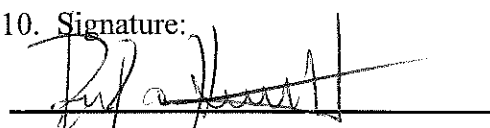
6. the *seventh* of December, 2009

7. by *Assistant Authentication Officer, United States Department of State*

8. No. *10007168-7*

9. Seal/Stamp:

10. Signature:


Patrick O. Hatchett

Name of Product(s)	Name of Manufacturer/Distributor Address
--------------------	---

ARGYLE Carotid Artery Shunt Kits

8888577700 CAROTID ARTERY SHUNT
8888577775 CAROTID ARTERY SHUNT

ARGYLE Ferguson Thoracic Catheters

8888572040 FERG THORACIC 28 FR
8888572057 FERG THORACIC 32 FR
8888572065 FERG THORACIC 36 FR

ARGYLE Left Ventricular Sump Vent Catheters

8888590216 5902-18 LEFT VENT 18 FR
8888590208 5902-14 LEFT VENT 14 FR
8888590224 5902-20 LEFT VENT 20 FR

ARGYLE Dual Lumen PICC Catheters & Trays

43304 1.9 FR ARGYLE DUAL LUMEN PICC
43308 PICC INSERTION TRAY NO INTRO
43311 DUAL LUMEN INSERTION TRAY

ARGYLE Peel-Away PICC Cannula Introducer

43320 PEEL-AWAY CANNULA INTRODUCER

ARGYLE Single Lumen PICC Catheters & Trays

43303 1.9F ARGYLE SINGLE LUMEN PICC
43309 SINGLE LUMEN INSERTION TRAY

ARGYLE NEO-SERT Umbilical Vessel Catheter Insertion Trays

8888160408 UVC TRAY/NO CATHETER
8888160424 UVC TRAY/3.5FR PU
8888160432 UVC TRAY/5.0 FR PU
8888160440 UVC TRAY/3.5FR PVC
8888160457 UVC TRAY/5.0FR PVC
8888160838 3.5FR DUAL-LMN UVC INSR TRY
8888160853 5FR DUAL-LUMN UVC INSRT TRY
8888160119 3.5/5.0FR PU UVC TRAY
43201 SAFETY NEO-SERT UVC TRAY W/O C
160409 UMBCL VSL CATH KIT W/SMOOTH TIP

"END OF PAGE"

Legal Manufacturer:

Kendall, a division of Tyco Healthcare Group LP
15 Hampshire Street
Mansfield, MA 02048

Manufacturing Facility:

Kendall, a division of Tyco Healthcare Group LP
5439 State Route 40
Argyle, NY 12809



Name of Product(s)	Name of Manufacturer/Distributor Address
--------------------	---

ARGYLE Umbilical Vessel Catheters (PVC)

8888160218	1602-3 UMBIL CATH 3.5 FR
8888160226	1602-5 UMBIL CATH 5 FR
8888160234	1602-8 UMBIL CATH 8 FR

Legal Manufacturer:

Kendall, a division of Tyco Healthcare Group LP
15 Hampshire Street
Mansfield, MA 02048

ARGYLE Umbilical Vessel Catheters with Hub (PVC)

8888160358	3.5 FR PVC UVC WITH HUB
8888160366	5.0 FR PVC UVC WITH HUB
8888160374	8.0 FR PVC UVC WITH HUB

Manufacturing Facility:

Kendall, a division of Tyco Healthcare Group LP
5439 State Route 40
Argyle, NY 12809

ARGYLE Umbilical Vessel Catheters with Hub

8888160325	2.5FR URETHANE UMB CATH
8888160333	3.5FR URETHANE UMB CATH
8888160341	5.0FR URETHANE UMB CATH

ARGYLE Umbilical Vessel Dual Lumen Catheters with Hub

8888160531	3.5FR DUAL-LUMEN UVC CATH
8888160556	5FR DUAL-LUMEN UVC CATH

ARGYLE Umbilical Vessel Triple Lumen Catheters with Hub

8888160648	5FR TRPL-LUMN UMB VSL CATH
8888160663	8FR TRPL-LUMN UMB VSL CATH

CURITY Urodynamic Dual Lumen Catheters

6427	6427 DUAL LUMEN CATH 7FR
6429	6429 DUAL LUMEN CATH 10FR

CURITY Urodynamic Triple Lumen Catheters

6437	6437 TRIPLE LUMEN CATH 7FR
6439	6439 TRIPLE LUMEN CATH 10FR

ECMO Catheter

5914	5914 ECMO CATH 14FR
------	---------------------

Ferguson Left Ventricular Vent Catheter

8888590018	FERG LEFT VENT 18 FR
------------	----------------------

MAHURKAR 8Fr. Dual Lumen Catheter Kits (Curved)

8832539006	KIT 8FX12 CE MAHURKAR
8832539007	KIT 8FX15 CE MAHURKAR

MAHURKAR 8Fr. Dual Lumen Catheter Kits (Straight)

8832539001	KIT 8FX9CM MAHURKAR
8832539002	KIT 8FX12CM MAHURKAR
8832539003	KIT 8FX15CM MAHURKAR

“END OF PAGE”



Name of Product(s)	Name of Manufacturer/Distributor Address
--------------------	---

**MAHURKAR 10.5Fr. Dual Lumen Catheters & Kits
with Side Holes (Straight Extensions)**

8817142005	CT 10FX12CM MAHURKAR SE CATH
8817145005	CT 10FX15CM MAHURKAR SE CATH
8817146001	KIT 10FX15CM MAHURKAR

Legal Manufacturer:

Kendall, a division of Tyco Healthcare Group LP
15 Hampshire Street
Mansfield, MA 02048

Manufacturing Facility:

Kendall, a division of Tyco Healthcare Group LP
5439 State Route 40
Argyle, NY 12809

MAHURKAR 11.5Fr. Dual Lumen Catheters & Kits (Straight)

8830414001	CT 11.5FX16 MAHURKAR
8830415001	KIT 11.5FX16 MAHURKAR
8813794005	CT 11.5FX19.5CM MAHURKAR
8831662001	CT 11.5FX24 MAHURKAR
8813816005	CT 11.5FX13.5CM MAHURKAR
8813793009	KIT 11.5FX19.5CM MAHURKAR
8813817005	KIT 11.5FX13.5CM MAHURKAR
8831661001	KIT 11.5FX24CM MAHURKAR

MAHURKAR 11.5Fr. Dual Lumen Catheter Kits & Trays (Pre-Curved)

8888115193	11.5FR X 19.5 PC MAHURKAR TRAY
8888115243	11.5FR X 24 PC MAHURKAR TRAY
8888115132	11.5FR X 13.5 PC MAHURKAR KIT
8888115163	11.5FR X 16 PC MAHURKAR TRAY
8888115242	11.5FR X 24 PC MAHURKAR KIT
8888115133	11.5FR X 13.5 PC MAHURKAR TRAY
8888115192	11.5FR X 19.5 PC MAHURKAR KIT
8888115162	11.5FR X 16 PC MAHURKAR KIT

MAHURKAR 11.5Fr. Dual Lumen Catheter Trays (Curved)

8817277011	TRAY 11.5FX13.5 CE MAHURKAR
8830416003	TRAY 11.5FX16 CE MAHURKAR
8815668011	TRAY 11.5FX19.5 CE MAHURKAR
8831663002	TRAY 11.5FX24 CE MAHURKAR

MAHURKAR 11.5Fr. Dual Lumen Catheter Trays (Straight)

8815668007	TRAY 11.5FX19.5 MAHURKAR
8817277007	TRAY 11.5FX13.5 MAHURKAR
8830416001	TRAY 11.5FX16 MAHURKAR
8831663001	TRAY 11.5FX24C MAHURKAR

MAHURKAR 11.5Fr. Dual Lumen Catheter Kits & Trays with VITACUFF (Curved)

8813793014	KIT 11.5FX19.5 CE VC MAHURKAR
8813817010	KIT 11.5X13.5 CE VC MAHURKAR
8815668012	TR 11.5FX19.5 CE VC MAHURKAR
8817277012	TR 11.5FX13.5 CE VC MAHURKAR
8830415004	KIT 11.5FX16 CE VC MAHURKAR
8830416004	MAHURKAR 11.5FX16 CE VC TRAY

"END OF PAGE"



Name of Product(s)	Name of Manufacturer/Distributor Address
--------------------	---

MAHURKAR 11.5Fr. Dual Lumen Catheter Kits & Trays with VITACUFF (Straight)

8813793011	KIT 11.5FX19.5 VC MAHURKAR
8813817007	KIT 11.5FX13.5 VC MAHURKAR
8817277009	TRAY 11.5FX13.5 VC MAHURKAR
8830415002	KIT 11.5FX16 VC MAHURKAR
8830416002	TRAY 11.5FX16 VC MAHURKAR
8815668009	TRAY 11.5FX19.5 VC MAHURKAR

Legal Manufacturer:

Kendall, a division of Tyco Healthcare Group LP
15 Hampshire Street
Mansfield, MA 02048

Manufacturing Facility:

Kendall, a division of Tyco Healthcare Group LP
5439 State Route 40
Argyle, NY 12809

MAHURKAR 12Fr. Triple Lumen Catheter

8888106000	12 FR. X 80 CMS W/O TIP
------------	-------------------------

MAHURKAR 12Fr. Triple Lumen Catheters, Kits & Trays (Curved)

8888101002	12FR X 16CM TRIPLE MAH TRAY
8888345603	ACUTE TRIPLE LUMEN KIT 13CM
8888345611	ACUTE TRIPLE LUMEN KIT 16CM
8888345538	ACUTE TRIPLE LUMEN CATH 24CM
8888101003	12FR X 20CM TRIPLE MAH TRAY
8888101004	12FR X 24CM TRIPLE MAH TRAY
8888345504	13CM ACUTE TRIPLE LUMEN CATH
8888345512	ACUTE TRIPLE LUMEN CATH 16CM
8888345629	ACUTE TRIPLE LUMEN KIT 20CM
8888345520	ACUTE TRIPLE LUMEN CATH 20CM
8888101001	12FR X 13CM TRIPLE MAH TRAY
8888345637	ACUTE TRIPLE LUMEN KIT 24CM

MAHURKAR 12Fr. Triple Lumen Catheters, Kits & Trays (Straight)

8888102003	20CM 12FR MAHRKR TLC TRAY W/SE
8888102004	24CM 12FR MAHRKR TLC TRAY W/SE
8888340629	12FRX20CM MAHKR TLC KIT SGTEXT
8888340637	12FRX24CM MAHKR TLC KIT SGTEXT

MAHURKAR 13.5Fr. Catheter Trays (Pre-Curved)

8888135136	MAHURKAR 13.5FRX13.5CM PC TRAY
8888135166	MAHURKAR 13.5FRX16CM PC TRAY
8888135196	MAHURKAR 13.5FRX19.5CM PC TRAY
8888135246	MAHURKAR 13.5FRX24CM PC TRAY

MAHURKAR 13.5Fr. Cuffed Catheters & Kits

8833052001	TRAY 13.5FX36 MAHURKAR CFFD
8833074004	KIT 13.5FX50 MAHURKAR CUFFD
8833052002	TRAY 13.5FX40 MAHURKAR CFFD
8888073003	MAHURKAR 13.5F X 45CM RK
8833074002	KIT 13.5FX40 MAHURKAR CUFFD
8833074001	KIT 13.5FX36 MAHURKAR CFFD
8833052003	TRAY 13.5FX45 MAHURKAR CFFD

“END OF PAGE”



Name of Product(s)	Name of Manufacturer/Distributor Address
--------------------	---

MAHURKAR Dual Lumen Catheters & Kits (Curved)

8813793013	KIT 11.5FX19.5 CE MAHURKAR
8813794009	CT 11.5FX19.5 CE MAHURKAR
8813816009	CT 11.5FX13.5 CE MAHURKAR
8813817009	KIT 11.5FX13.5 CE MAHURKAR
8817143005	KIT 10FX12CM CE MAHURKAR
8817146007	MAHURKAR 10FRX15 CE KIT
8817149007	KIT 10FX19.5 CE MAHURKAR
8817145007	CT 10FX15C CE MAHURKAR
8830414002	CT 11.5FX16 CE MAHURKAR
8830415003	KIT 11.5FX16 CE MAHURKAR

Legal Manufacturer:

Kendall, a division of Tyco Healthcare Group LP
15 Hampshire Street
Mansfield, MA 02048

Manufacturing Facility:

Kendall, a division of Tyco Healthcare Group LP
5439 State Route 40
Argyle, NY 12809

MAHURKAR Dual Lumen Catheter Kits with Side Holes & VITACUFF

8817143006	KIT 10FX12C CE VC MAHURKAR
8817146008	KIT 10FX15C CE VC MAHURKAR
8817149008	KIT 10FX19.5 CE VC MAHURKAR

MAHURKAR Dual Lumen Catheter Kits with 5cc Syringe (Curved)

8813053013	MAHURKAR 11.5X19 CE KIT W/5CC
8832059007	MAHURKAR 8X15 CE KIT W/5CC

MAHURKAR Dual Lumen Catheter Kits with 5cc Syringe (Straight)

8813053009	MAHURKAR 11.5X19 SE KIT W/5CC
8832059003	MAHURKAR 8X15 SE KIT W/5CC

MAHURKAR MAXID 14.5Fr. Dual Lumen Cuffed Catheter Kits, Trays & Sport Packs with Side Holes

8888145251	MAXID 19/36 KIT W/SIDEHOLES
8888145255	MAXID 19/36 TRAY W/SIDEHOLES
8888145252	MAXID 23/40 KIT W/SIDEHOLES
8888145254	MAXID 33/50 KIT W/SIDEHOLES
8888145256	MAXID 23/40 TRAY W/SIDEHOLES
8888145258	MAXID 33/50 TRAY W/SIDEHOLES
8888133535	MAXID SPORT PACK 33/50 W
8888119385	MAXID SPORT PACK 19/36 W
8888123435	MAXID SPORT PACK 23/40 W
8888128485	MAXID SPORT PACK 28/45 W
8888145257	MAXID 28/45 TRAY W/SIDEHOLES
8888145253	MAXID 28/45 KIT W/SIDEHOLES

"END OF PAGE"



Name of Product(s)	Name of Manufacturer/Distributor Address
--------------------	---

**MAHURKAR MAXID 14.5Fr. Dual Lumen Cuffed Catheter Kits, Trays & Sport Packs
without Side Holes**

8888145002	MAXID 23/40 KIT W/OUT SIDEHOL
8888145007	MAXID 28/45 TRAY W/OUT SIDEHOL
8888119380	MAXID SPORT PACK 19/36 W/O
8888145004	MAXID 33/50 KIT W/OUT SIDEHOL
8888128480	MAXID SPORT PACK 28/45 W/O
8888145001	MAXID 19/36 KIT W/OUT SIDEHOL
8888123430	MAXID SPORT PACK 23/40 W/O
8888145006	MAXID 23/40 TRAY W/OUT SIDEHOL
8888145008	MAXID 33/50 TRAY W/OUT SIDEHOL
8888145005	MAXID 19/36 TRAY W/OUT SIDEHOL
8888145003	MAXID 28/45 KIT W/OUT SIDEHOL

Legal Manufacturer:

Kendall, a division of Tyco Healthcare Group LP
15 Hampshire Street
Mansfield, MA 02048

Manufacturing Facility:

Kendall, a division of Tyco Healthcare Group LP
5439 State Route 40
Argyle, NY 12809

**MAHURKAR MAXID 14.5Fr. Dual Lumen Cuffed Catheter Kits, Trays & Sport Packs
with Sheathless Insertion Device**

8888119362	MAXID 19/36 W/SH SPRT W/VT
8888123402	MAXID 23/40 W/SH SPRT W/VT
8888128452	MAXID 28/45 W/SH SPRT W/VT
8888133502	MAXID 33/50 W/SH SPRT W/VT
8888145019	MAXID 19/36 KIT W/SLESS
8888145020	MAXID 23/40 KIT W/SLESS
8888145021	MAXID 28/45 KIT W/SLESS
8888145022	MAXID 33/50 KIT W/SLESS
8888145031	MAXID 19/36 W/SH TRAY W/VT
8888145032	MAXID 23/40 W/SH TRAY W/VT
8888145033	MAXID 28/45 W/SH TRAY W/VT
8888145034	MAXID 33/50 W/SH TRAY W/VT
8888145027	MAXID 19/36 W/SH KIT W/VT
8888145028	MAXID 23/40 W/SH KIT W/VT
8888145029	MAXID 28/45 W/SH KIT W/VT
8888145030	MAXID 33/50 W/SH KIT W/VT

MAHURKAR QPLUS Dual Lumen Catheters & Trays (Curved)

8888135192	MAHURKAR 13.5FRX19.5CM CE KIT
8888135135	MAHURKAR 13.5FRX13.5CM CE TRAY
8888135132	MAHURKAR 13.5FRX13.5CM CE KIT
8888135162	MAHURKAR 13.5FRX 16CM CE KIT
8888135195	MAHURKAR 13.5FRX19.5CM CE TRAY
8888135242	MAHURKAR 13.5FRX24CM CE KIT
8888135245	MAHURKAR 13.5FRX24CM CE TRAY
8888135165	MAHURKAR 13.5FRX16CM CE TRAY

MAHURKAR QPLUS Dual Lumen Catheters (Pre-Curved)

8888135133	MAHURKAR 13.5FRX13.5CM PC KIT
8888135163	MAHURKAR 13.5FRX16CM PC KIT
8888135243	MAHURKAR 13.5FRX24CM PC KIT
8888135193	MAHURKAR 13.5FRX19.5CM PC KIT

“END OF PAGE”



Name of Product(s)	Name of Manufacturer/Distributor Address
--------------------	---

MAHURKAR QPLUS Dual Lumen Catheters & Trays (Straight)

8888135131	MAHURKAR 13.5FRX13.5CM SE KIT
8888135194	MAHURKAR 13.5FRX19.5CM SE TRAY
8888135164	MAHURKAR 13.5FRX16CM SE TRAY
8888135191	MAHURKAR 13.5FRX19.5CM SE KIT
8888135241	MAHURKAR 13.5FRX 24CM SE KIT
8888135244	MAHURKAR 13.5FRX24CM SE TRAY
8888135161	MAHURKAR 13.5FR X 16CM SE KIT
8888135134	MAHURKAR 13.5FRX13.5CM SE TRAY

Legal Manufacturer:

Kendall, a division of Tyco Healthcare Group LP
15 Hampshire Street
Mansfield, MA 02048

Manufacturing Facility:

Kendall, a division of Tyco Healthcare Group LP
5439 State Route 40
Argyle, NY 12809

PALINDROME 14.5Fr. Catheter Kits & Sport Packs with Slots

8888145016	PALINDROME 28/45 KIT W/ SLOT
8888145013	TAL PALINDROME 55/75 KIT
8888145017	PALINDROME 33/50 KIT W/ SLOT
8888133500	PALINDROME 33/50 SPORT W/ SLOT
8888145018	PALINDROME 55/72 KIT W/ SLOT
8888128450	PALINDROME 28/45 SPORT W/ SLOT
8888123400	PALINDROME 23/40 SPORT W/ SLOT
8888145014	PALINDROME 19/36 KIT W/ SLOT
8888119360	PALINDROME 19/36 SPORT W/ SLOT
8888145015	PALINDROME 23/40 KIT W/ SLOT

PALINDROME 14.5Fr. Cuffed Catheter Kits & Sport Packs with Slots & Sheathless Insertion Device

8888119364	PALIND 19/36 SLOT SPRT W/VT
8888123404	PALIND 23/40 SLOT SPRT W/VT
8888128454	PALIND 28/45 SLOT SPRT W/VT
8888133504	PALIND 33/50 SLOT SPRT W/VT
8888145039	PALIND 19/36 SLOT KIT W/VT
8888145040	PALIND 23/40 SLOT KIT W/VT
8888145041	PALIND 28/45 SLOT KIT W/VT
8888145042	PALIND 33/50 SLOT KIT W/VT

PALINDROME Pre-Curved Catheter Kits & Sport Packs

8888119370	PC PALINDROME 19/36 SPT W/SLOT
8888123410	PC PALINDROME 23/40 SPT W/SLOT
8888128460	PC PALINDROME 28/45 SPT W/SLOT
8888145061	PC PALINDROME 33/50 KIT W/SLOT
8888145058	PC PALINDROME 19/36 KIT W/SLOT
8888145059	PC PALINDROME 23/40 KIT W/SLOT
8888145060	PC PALINDROME 28/45 KIT W/SLOT
8888133510	PC PALINDROME 33/50 SPT W/SLOT

PERMCATH PULL-APART Introducer Set

8815544013	Oval PULL-APART Introducer Set
------------	--------------------------------

QUINTON 2 Part Titanium Luer Adapter

8888415604	2 Part Titanium Connector
------------	---------------------------

"END OF PAGE"

