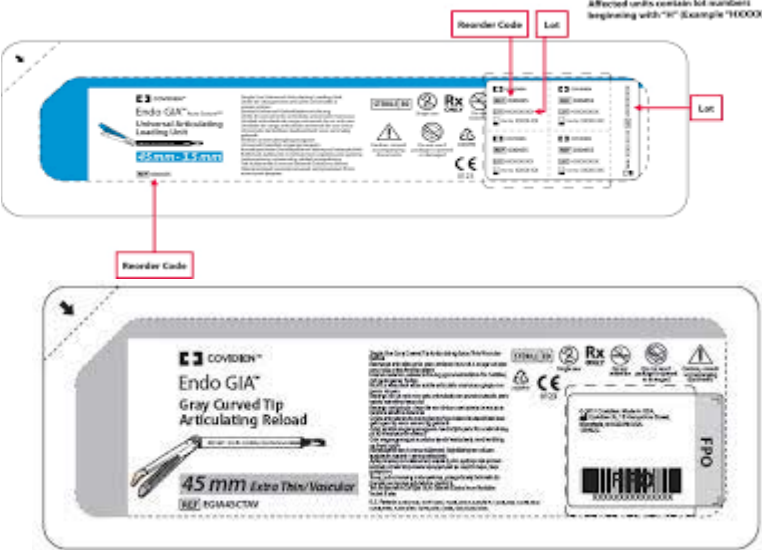


## Urgent Safety Communication

### Urgent FSN's of Covidien Endo GIA™ Articulating Loading Units Manufactured by Medtronic

<b>Device/ Product Name:</b>	Covidien Endo GIA™ Articulating Loading Units
<b>Lot numbers/Serials:</b>	The attached file contain the affected item codes and lot numbers.
<b>Manufacturer:</b>	Medtronic
<b>Problem:</b>	Saudi FDA would like to bring your attention that <b>Medtronic</b> is issuing an <b>Urgent FSN's</b> to inform about the potential for a <b>device</b> to be missing the sled component. The sled component is responsible for staple deployment. Without the sled, no staples would be deployed. Use of a product with this issue may result in failure to form a staple line when tissue is divided, leading to bleeding or leakage of luminal contents. Medtronic has received four reports of injury related to this issue
<b>Recommendation/Actions:</b>	<p>Medtronic recommends the following actions , Please:</p> <ol style="list-style-type: none"> <li>1. Immediately discontinue use, and quarantine the affect item codes and lots listed on Attachment A and B.</li> <li>2. Return affected product as indicated in the FSN's.</li> <li>3. Complete the Return Verification Form even if you do not have inventory.</li> </ol>

<p><b>Devices/Products photo:</b></p>		
<p><b>Authorized Representative Details</b></p>	<p><b>Company name:</b></p>	<p><b>Medtronic Saudi Arabia Co.</b></p>
	<p><b>Contact Person:</b></p>	<p><b>Quality and Regulatory Affairs dep.</b></p>
	<p><b>Phone:</b></p>	<p><b>+966 114048884</b></p>
	<p><b>Email:</b></p>	<p><a href="mailto:ksa.ra@medtronic.com">ksa.ra@medtronic.com</a></p>

For further information, please **see the FSN below or [Click Here.](#)**

Healthcare Professionals should report any adverse events suspected to be associated with affected devices above (or other Medical Devices) to:

**National Center for Medical Devices Reporting.**

Medical Devices Sector  
Saudi Food and Drug Authority  
Postal Address: Saudi Arabia - Saudi Food and Drug Authority (3292)  
North Ring Road - Al Nafal Unit (1)  
Riyadh 13312 - 6288  
Tel: +966 (11) 2038222 Ext: 2406, 2412  
Fax: +966 (11) 2757245

For latest published Recalls/Alerts, please visit ([NCMDR Website](#))

Sincerely,  
NCMDR Team

## **URGENT FIELD SAFETY NOTICE** **Covidien Endo GIA™ Articulating Loading Units**

May 2018

Medtronic reference: FA816

### **Attention: Risk Management Director and O.R. Materials Management**

Dear Valued Customer:

The purpose of this letter is to advise you that Medtronic is voluntarily recalling specific production lots of its Covidien Endo GIA™ Articulating Loading Units.

### **Issue Description:**

This voluntary recall is being conducted due to the potential for a device to be missing the sled component. The sled component is responsible for staple deployment. Without the sled, no staples would be deployed. Use of a product with this issue may result in failure to form a staple line when tissue is divided, leading to bleeding or leakage of luminal contents. Medtronic has received four reports of injury related to this issue.

This voluntary recall affects only the item codes and lots listed on Attachment A & B (FOR USE IN EU ONLY).

Medtronic requests that you immediately discontinue use of the affected products detailed on Attachment A and B (FOR USE IN EU ONLY). Please quarantine and return any unused products of the listed item codes and lots. Unused products from the affected item codes and lots should be returned as described in the Required Actions section below. If you have distributed Endo GIA™ devices listed on Attachment A and B (FOR USE IN EU ONLY) please promptly forward the information from this letter to those recipients. All unused products from the affected item codes and lots must be returned.

### **Required Actions:**

1. Please immediately discontinue use, and quarantine the affected item codes and lots listed on Attachment A and B (FOR USE IN EU ONLY).
2. Please return affected product as indicated below.
3. Complete the Return Verification Form **even if you do not have inventory**.

	Customer with inventory	Customer with zero inventory	Where to send the completed form
Purchased directly from <b>Medtronic</b>	Please complete the attached Returns Verification Form in its entirety. Upon receiving your form, Medtronic Customer Care will contact you to organize the return of your products. You will receive credit for unused device(s) that you return.	Complete form and check the box indicating "no inventory"	E-mail or fax the completed form to the Medtronic contact provided on the verification form.
Purchased from a <b>distributor</b>	Complete <b>all</b> fields on the form and contact your distributor directly to arrange for return of product	Complete form and check the box indicating "no inventory"	E-mail or fax the completed form to your Distributor & to the Medtronic contact provided on the verification form.

The Competent Authority of your country has been notified of this action. Please maintain a copy of this notice in your records.

We request that you contact Medtronic if you experienced quality problems or adverse events.

We regret any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter. If you have any questions regarding this communication, please contact your Medtronic representative.

Sincerely,

Medtronic Saudi Arabia LLC

### Attachment A

Item Code	Item Description	Affected Lots		
030450	Endo GIA™ Auto Suture™ Universal Articulating Loading Unit 30mm- 2.0mm	N7L0306KX N7M0221KX	N8B0724KX N8C0958KX	N8C1303KRX
030451	Endo GIA™ Auto Suture™ Universal Articulating Loading Unit 30mm - 2.5mm	N7L0071KX N7L0527KX N7L0792KX N7L0914KX N7L1014KX N7L1159KX	N7M0464KX N7M0786KX N8A0154KX N8A0553KX N8A0850KX	N8A1014KX N8B0304KX N8C0830KX N8C0847KRX N8C0848KRX
030452	Endo GIA™ Auto Suture™ Universal Articulating Loading Unit 30mm - 3.5mm	N7L0191KX N7M0944KX	N8B0234KX	N8C0147KX
030454	Endo GIA™ Auto Suture™ Universal Articulating Loading Unit 45mm - 2.5mm	N7K1146KX N7L0355KX N7L1119KX N7M0088KX N7M0343KX N7M0477KRX	N7M0509KX N7M0520KX N7M0521KX N8A0312KRX N8A0360KX N8A0433KX	N8A0434KX N8A0435KX N8B0487KX N8C0026KX N8C0119KX N8C0630KX
030455	Endo GIA™ Auto Suture™ Universal Articulating Loading Unit 45mm- 3.5mm	N7F0576KX N7L0032KX N7L0239KX N7L0519KX N7M0104KX	N7M0383KX N7M0584KX N7M0696KX N8A0036KX	N8A0324KX N8A0477KRX N8A0551KX N8C0357KX
030457	Endo GIA™ Auto Suture™ Universal Articulating Loading Unit 60mm -2.5mm	N7D0492KRX N7F0518KX N7F0651KX N7L0270KX	N7L0699KX N7L0732KX N7L1043KX	N8A0213KX N8B0002KX N8C0429KX
030458	Endo GIA™ Auto Suture™ Universal Articulating Loading Unit 60mm - 3.5mm	N7F0631KX N7L0117KX N7L0397KX N7L0465KX N7L0768KX N7L0911KX N7L1075KX N7M0067KX N7M0314KX	N7M0646KX N7M0740KX N7M0972KX N8A0172KX N8A0539KX N8A0679KX N8A0910KX N8A0961KX N8B0054KX	N8B0099KX N8C0008KX N8C0205KX N8C0532KX N8C0571KX N8C0758KX N8C0795KX N8C1284KRX
EGIA30CTAV	Endo GIA™ 30mm Gray Curved Tip Articulating Vascular Reload with Tri-Staple™ Technology	N7G0756KX		
EGIA30AV	Endo GIA™ 30mm Gray Articulating Vascular Reload with Tri-Staple™ Technology	N7G0757KX		
EGIA45CTAV	Endo GIA™ 45mm Gray Curved Tip Articulating Vascular Reload with Tri-Staple™ Technology	N7G0796KX		

**Attachment B**

**For use in EU countries where Kits were distributed**

Item Code	Kit Description	Affected lots
SLEEVEGK3	BOX SLEEVEGK3	0215050387
SLEEVEGK3	BOX SLEEVEGK3	0215193250
01KBAR006116V	BOX 01KBAR006116V PROC BYPASS 01KBAR0061	0214710711
KITDE0143	BOX KITDE0143 BYPASS BOX	0214463634
KITDE0143	BOX KITDE0143 BYPASS BOX	0215280952
KITDE0108	BOX KITDE0108 BYPASS KIT LUEBECK	0214894171
KIT1095V	BOX KIT1095V KIT OBESITAS	0214062622
KITDE0154	BOX KITDE0154 BYPASS KH NORTHWEST	0214013887
KITDE0154	BOX KITDE0154 BYPASS KH NORTHWEST	0214144177
KITDE0154	BOX KITDE0154 BYPASS KH NORTHWEST	0214260194
KITDE0154	BOX KITDE0154 BYPASS KH NORTHWEST	0214470767
KITDE0154	BOX KITDE0154 BYPASS KH NORTHWEST	0214620382
KITDE0154	BOX KITDE0154 BYPASS KH NORTHWEST	0214744957
KITDE0154	BOX KITDE0154 BYPASS KH NORTHWEST	0214956044
KITDE0154	BOX KITDE0154 BYPASS KH NORTHWEST	0215079103
KITDE0154	BOX KITDE0154 BYPASS KH NORTHWEST	0215151206
KIT1171C	BOX KIT1171C KIT LAP CYSTECTOMY	0214090852
KIT1171C	BOX KIT1171C KIT LAP CYSTECTOMY	0214522213
KIT1171C	BOX KIT1171C KIT LAP CYSTECTOMY	0215009132
KIT1171C	BOX KIT1171C KIT LAP CYSTECTOMY	0215153445
PST01199	BOX PST01199 BARIATRIC TRISTAPLE	0214109631
PST01199	BOX PST01199 BARIATRIC TRISTAPLE	0214909770
VATS1SCDX	BOX VATS1SCDX DO ZABIEGOW VATS	0214874566
VATS1SCDX	BOX VATS1SCDX DO ZABIEGOW VATS	0215001737
VATS1SCDX	BOX VATS1SCDX DO ZABIEGOW VATS	0215151361
KIT00713	BOX KIT00713 KIT BY PASS	0215234651
KIT00713	BOX KIT00713 KIT BY PASS	0215288296
KIT00713	BOX KIT00713 KIT BY PASS	0214364763
KIT00713	BOX KIT00713 KIT BY PASS	0214456590
KIT00713	BOX KIT00713 KIT BY PASS	0214435328
KIT00713	BOX KIT00713 KIT BY PASS	0214983139
KIT00713	BOX KIT00713 KIT BY PASS	0215042012
KIT00714	BOX KIT00714 KIT SLEEVE	0215159225
KIT00714	BOX KIT00714 KIT SLEEVE	0215234652
KIT00714	BOX KIT00714 KIT SLEEVE	0214915642
KIT00714	BOX KIT00714 KIT SLEEVE	0214983138
TGGLOGOWX1	BOX TGGLOGOWX1 DO TOTAL GASTRECTOMIII	0214726876
BOX1073180APPE1	BOX BOX1073180APPE1 APPENDIX KIT ZAMS	0214050554

Item Code	Kit Description	Affected lots
BOX1073180APPE1	BOX BOX1073180APPE1 APPENDIX KIT ZAMS	0214991119
BOX1073180APPE1	BOX BOX1073180APPE1 APPENDIX KIT ZAMS	0215130754
BOX1073180APPE1	BOX BOX1073180APPE1 APPENDIX KIT ZAMS	0215158268
SLEEVEJAWI	BOX SLEEVEJAWI SLEEVE GASTRECTOMY BOX	0214030210
SLEEVEJAWI	BOX SLEEVEJAWI SLEEVE GASTRECTOMY BOX	0215041719
SLEEVEJAWI	BOX SLEEVEJAWI SLEEVE GASTRECTOMY BOX	0215161529
SLEEVEJAWI	BOX SLEEVEJAWI SLEEVE GASTRECTOMY BOX	0215272924
VATSLOB11	BOX VATSLOB11 ZESTAW DO VATS LOBECTOMII	0214866335
VATSLOB11	BOX VATSLOB11 ZESTAW DO VATS LOBECTOMII	0214993030
VATSLOB11	BOX VATSLOB11 ZESTAW DO VATS LOBECTOMII	0215178525
LAPPH	BOX LAPPH ZASTAW DO PRAW EJ HEMIKOLEKTOMI	0215015272
LAPPH	BOX LAPPH ZASTAW DO PRAW EJ HEMIKOLEKTOMI	0215298205
LAPGAR	BOX LAPGAR ZESTAW DO GB35	0214049704
LAPGAR	BOX LAPGAR ZESTAW DO GB35	0214529057
LAPGAR	BOX LAPGAR ZESTAW DO GB35	0215176564
LAPZD	BOX LAPZD ZESTAW DO SG	0215082707
LAPZD	BOX LAPZD ZESTAW DO SG	0215176563
BOX1073076GASB0	BOX BOX1073076GASB0 BBR STVEIT GASTRIC B	0214043771
BOX1073076GASB0	BOX BOX1073076GASB0 BBR STVEIT GASTRIC B	0214232317
BOX1073076GASB0	BOX BOX1073076GASB0 BBR STVEIT GASTRIC B	0214375093
BOX1073076GASB0	BOX BOX1073076GASB0 BBR STVEIT GASTRIC B	0215113531
BOX1073076GASB0	BOX BOX1073076GASB0 BBR STVEIT GASTRIC B	0215132607
KITDE0183	BOX KITDE0183 APPENDIX LIPPE DETMOLD	0214014173
KITDE0183	BOX KITDE0183 APPENDIX LIPPE DETMOLD	0214573291
KITDE0183	BOX KITDE0183 APPENDIX LIPPE DETMOLD	0214621781
KITDE0183	BOX KITDE0183 APPENDIX LIPPE DETMOLD	0214909631
KITDE0183	BOX KITDE0183 APPENDIX LIPPE DETMOLD	0215068744
KITDE0183	BOX KITDE0183 APPENDIX LIPPE DETMOLD	0215068743
KITDE0183	BOX KITDE0183 APPENDIX LIPPE DETMOLD	0215068743
KITDE0183	BOX KITDE0183 APPENDIX LIPPE DETMOLD	0215108743
KITDE0183	BOX KITDE0183 APPENDIX LIPPE DETMOLD	0215108744
KITDE0183	BOX KITDE0183 APPENDIX LIPPE DETMOLD	0215276369
LAPIMBGP1	BOX LAPIMBGP1 ZESTAW DO MGBP	0214793818
LAPIMBGP1	BOX LAPIMBGP1 ZESTAW DO MGBP	0214930629
LAPIMBGP1	BOX LAPIMBGP1 ZESTAW DO MGBP	0214993038
LAPIMBGP1	BOX LAPIMBGP1 ZESTAW DO MGBP	0215068848
LAPIMBGP1	BOX LAPIMBGP1 ZESTAW DO MGBP	0215124286
LAPIMBGP1	BOX LAPIMBGP1 ZESTAW DO MGBP	0215124285

LAPIMBGP1	BOX LAPIMBGP1 ZESTAW DO MGBP	0215130759
LAPIMBGP1	BOX LAPIMBGP1 ZESTAW DO MGBP	0215243237

Item Code	Kit Description	Affected lots
LAPISG1	BOX LAPISG1 ZESTAW DO SG	0214793817
LAPISG1	BOX LAPISG1 ZESTAW DO SG	0214930628
LAPISG1	BOX LAPISG1 ZESTAW DO SG	0214930630
LAPISG1	BOX LAPISG1 ZESTAW DO SG	0214993037
LAPISG1	BOX LAPISG1 ZESTAW DO SG	0215068849
LAPISG1	BOX LAPISG1 ZESTAW DO SG	0215124284
LAPISG1	BOX LAPISG1 ZESTAW DO SG	0215243236
PST03403	BOX PST03403 ALTERNATIVE APPENDIX KIT	0214975597
SLEEVEGK4	BOX SLEEVEGK4 SLEEVE GASTRECTOMY	0214933111
PST03533	BOX PST03533 KIT APP STAPLER	0214860061
PST03533	BOX PST03533 KIT APP STAPLER	0215036238
PST03533	BOX PST03533 KIT APP STAPLER	0215036240
PST03533	BOX PST03533 KIT APP STAPLER	0215018854
PST03533	BOX PST03533 KIT APP STAPLER	0215018855
PST03533	BOX PST03533 KIT APP STAPLER	0215036239
PST03533	BOX PST03533 KIT APP STAPLER	0215102248
PST03533	BOX PST03533 KIT APP STAPLER	0215068746
PST03533	BOX PST03533 KIT APP STAPLER	0215050428
PST03533	BOX PST03533 KIT APP STAPLER	0215102247
PST03533	BOX PST03533 KIT APP STAPLER	0215102246
PST03533	BOX PST03533 KIT APP STAPLER	0215050429
PST03533	BOX PST03533 KIT APP STAPLER	0215068748
PST03533	BOX PST03533 KIT APP STAPLER	0215068747
PST03533	BOX PST03533 KIT APP STAPLER	0215050427
PST03533	BOX PST03533 KIT APP STAPLER	0215117409
PST03533	BOX PST03533 KIT APP STAPLER	0215117410
PST03533	BOX PST03533 KIT APP STAPLER	0215117411
PST03533	BOX PST03533 KIT APP STAPLER	0215125963
PST03533	BOX PST03533 KIT APP STAPLER	0215125962
PST03533	BOX PST03533 KIT APP STAPLER	0215125964
PST03533	BOX PST03533 KIT APP STAPLER	0215275313
PST03533	BOX PST03533 KIT APP STAPLER	0215275314
PST03533	BOX PST03533 KIT APP STAPLER	0215275315
PST03533	BOX PST03533 KIT APP STAPLER	0215282505
PST03533	BOX PST03533 KIT APP STAPLER	0215282506
PST03699	BOX PST03699 KIT APP MED ALTERNATIV STAP	0215050309
PST03699	BOX PST03699 KIT APP MED ALTERNATIV STAP	0215108007
PST03699	BOX PST03699 KIT APP MED ALTERNATIV STAP	0215050308



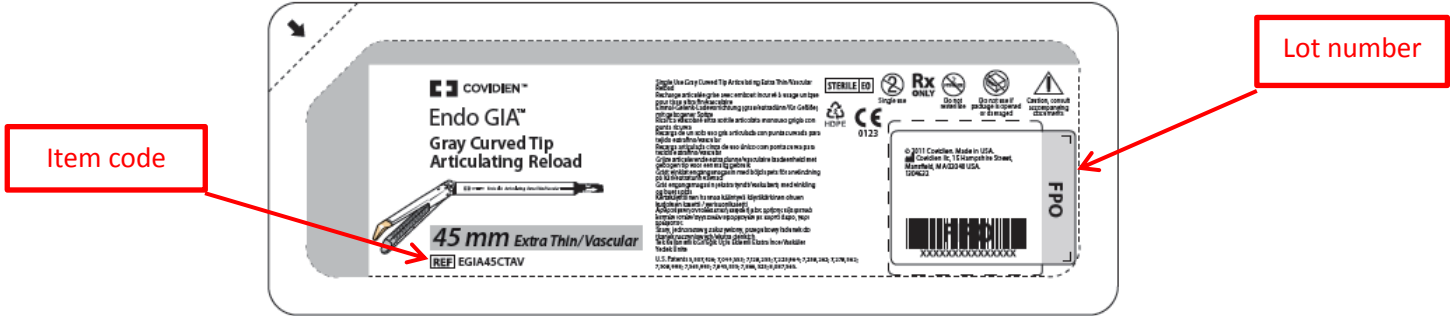
PST03699	BOX PST03699 KIT APP MED ALTERNATIV STAP	0215050310
PST03699	BOX PST03699 KIT APP MED ALTERNATIV STAP	0215108008

Item Code	Kit Description	Affected lots
PST03699	BOX PST03699 KIT APP MED ALTERNATIV STAP	0215050313
PST03699	BOX PST03699 KIT APP MED ALTERNATIV STAP	0215050312
PST03699	BOX PST03699 KIT APP MED ALTERNATIV STAP	0215050311
PST03699	BOX PST03699 KIT APP MED ALTERNATIV STAP	0215037144
PST03699	BOX PST03699 KIT APP MED ALTERNATIV STAP	0215037143
PST03627	BOX PST03627 BYPASS AIWA CLINIC	0214701832
PST03627	BOX PST03627 BYPASS AIWA CLINIC	0214999435
PST03627	BOX PST03627 BYPASS AIWA CLINIC	0214999435
LAPISGW	BOX LAPISGW ZESTAW DO SG	0215120700
SGGLOGX1	BOX SGGLOGX1 ZESTAW DO BARIATRII	0215017846
SGGLOGX1	BOX SGGLOGX1 ZESTAW DO BARIATRII	0215191012
HEMIGX1	BOX HEMIGX1 ZESTAW DO HEMICOLECTOMII	0214909888
HEMIGX1	BOX HEMIGX1 ZESTAW DO HEMICOLECTOMII	0214916144
MGBGLOGX1	BOX MGBGLOGX1 ZESTAW MINI GASTRIC BYPASS	0215124172
MGBGLOGX1	BOX MGBGLOGX1 ZESTAW MINI GASTRIC BYPASS	0215253056
SGSWP1	BOX SGSWP1 ZESTAW DO RESEKCI REKAWOWEJ	0215218687
PST04090	BOX PST04090 BYPASS AIWA CLINIC	0215282382
PST04090	BOX PST04090 BYPASS AIWA CLINIC	0215237527
PST04090	BOX PST04090 BYPASS AIWA CLINIC	0214991347
PST04090	BOX PST04090 BYPASS AIWA CLINIC	0214991348
PST04090	BOX PST04090 BYPASS AIWA CLINIC	0214991349
PST04089	BOX PST04089 SLEEVE AIWA CLINIC	0215237526
PST04089	BOX PST04089 SLEEVE AIWA CLINIC	0214991350
PST04089	BOX PST04089 SLEEVE AIWA CLINIC	0214991351
PST04089	BOX PST04089 SLEEVE AIWA CLINIC	0215157997
PST04089	BOX PST04089 SLEEVE AIWA CLINIC	0215157998
VMIN	BOX VMIN ZESTAW DO VATS PODSTAWOWY	0215122341
VMIN	BOX VMIN ZESTAW DO VATS PODSTAWOWY	0215226207
VWR	BOX VWR ZESTAW DO VATS KLIN	0215122344
BOX1073076GASB1	BOX BOX1073076GASB1 BBR GASTRIC BYPASS S	0215227169
KIT00486R	KIT00486R OBESIDAD D. WORWARLD 2 X1	0213984473
KIT00486R	KIT00486R OBESIDAD D. WORWARLD 2 X1	0213583578
KIT00486R	KIT00486R OBESIDAD D. WORWARLD 2 X1	0214068986
KIT00486R	KIT00486R OBESIDAD D. WORWARLD 2 X1	0213596057
KIT00486R	KIT00486R OBESIDAD D. WORWARLD 2 X1	0213589227
KIT4184	KIT4184 APEN LOBECTOMY KIT X1	0214962218
KITBAR021	KITBAR021- BARIATRIC KIT X1	0215065486
KIT-DE-0080	KIT-DE-0080 BYPASS KIT LOHNE X1	0214049646

KIT-DE-0080	KIT-DE-0080 BYPASS KIT LOHNE X1	0214370002
KIT-DE-0080	KIT-DE-0080 BYPASS KIT LOHNE X1	0214470664

Item Code	Kit Description	Affected lots
KIT-DE-0080	KIT-DE-0080 BYPASS KIT LOHNE X1	0215208426
KIT-DE-0083	KIT-DE-0083 APPENEKTOMIE KIT NAUENX1	0214618312
KIT-DE-0083	KIT-DE-0083 APPENEKTOMIE KIT NAUENX1	0214795633
KIT-DE-0083	KIT-DE-0083 APPENEKTOMIE KIT NAUENX1	0214798114
KIT-DE-0083	KIT-DE-0083 APPENEKTOMIE KIT NAUENX1	0215002022
KIT-DE-0083	KIT-DE-0083 APPENEKTOMIE KIT NAUENX1	0215010930
KIT-DE-0083	KIT-DE-0083 APPENEKTOMIE KIT NAUENX1	0215010931
KIT-DE-0083	KIT-DE-0083 APPENEKTOMIE KIT NAUENX1	0215010932
KIT-DE-0083	KIT-DE-0083 APPENEKTOMIE KIT NAUENX1	0215132611
KIT-DE-0083	KIT-DE-0083 APPENEKTOMIE KIT NAUENX1	0215132612
KIT-DE-0083	KIT-DE-0083 APPENEKTOMIE KIT NAUENX1	0215132613
KIT-DE-0083	KIT-DE-0083 APPENEKTOMIE KIT NAUENX1	0215264173
LAPBARLECZNA	LAPBARLECZNA ZESTAW BARIATRYCZNY LECZNA.	0215274505
SLEEVEGK1	SLEEVEGK1 ZESTAW DO ZABIEGOW SLEEVE X1	0215244887
SSLEEVE	SSLEEVE ZEST DO SLEEVE GASTREKTOMIIX1	0214985253
SSLEEVE	SSLEEVE ZEST DO SLEEVE GASTREKTOMIIX1	0215104506
SSLEEVE	SSLEEVE ZEST DO SLEEVE GASTREKTOMIIX1	0215298203
MGBX	MGBX ZESTAW GB LS X1	0215017845
MGBX	MGBX ZESTAW GB LS X1	0215002541
MGBX	MGBX ZESTAW GB LS X1	0215104507

# Attachment C



Item code

Lot number

Item code

Lot number

