



LIFE FROM INSIDE

17 August 2016

Dear Valued Customer,

Starting August 2016, Bracco Diagnostics Inc. will begin to transition the labeling of its medical device products, to comply with the U.S. Food and Drug Administration's regulation on Unique Device Identification (UDI). Bracco has adopted and incorporated GS1 Global Trade Identification Numbers (GTINs) as part of its UDI coding system. GS1 standards are globally utilized, by many different industries, to properly identify and track products (in this case, for medical devices) throughout the entire supply chain process. This shall enable you to drive efficiencies to support the traceability and accuracy of products by those facilities/hospitals that utilize bar code scanning.

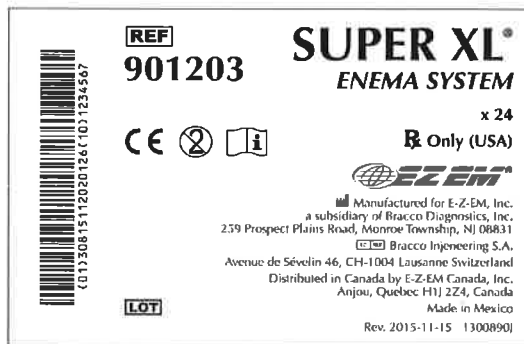
As you receive medical devices you will observe several distinct changes in our product labeling. Below is a sample of label revisions in which you will notice some differences:

- A new UDI compliant barcode replaces the legacy barcode.
- Where applicable, the legacy SKU numbers (i.e., E-Z-EM former four-digit number), have been replaced with the Bracco six-digit SKU number.
- The date format complies with new requirements (YYYY-MM-DD)

Current Label Sample



UDI Compliant Label Sample



For your convenience, enclosed you will find a GTIN cross-reference chart that includes a complete list of our products affected by GS1 standards. Each product is identified by both a Bracco and a former E-Z-EM SKU number and a product description. Please share this information with your receiving department to ensure they are aware of these changes and to help avoid any receiving delays.

Bracco Diagnostics understands and recognizes the importance of providing your patients with the safest care and products of the highest quality. We appreciate your continued business and patience during this transition.

If you would like more information about the FDA's GS1 standards please go to <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/default.htm>.

GTIN numbers listed by full packaging levels are available upon request.

If you have any questions regarding this communication please contact Customer Service at 877-272-2269 (877-Bracco9).

Regards,

Rob Zachow
Director, Trade Relations
Bracco Diagnostics Inc.

Bracco Diagnostics Inc.

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Bracco Group

GTIN Cross Reference Chart

Bracco Item Number	Legacy Item Number	Legacy GTIN	Product Name	New GTIN - UDI Compliant
000475	Not Applicable	10302700000050	Fluid Administration Set	30815112020010
000482	Not Applicable	10302700000067	Boekel Scientific Contrast Scientific Warmer	Class 1 Medical Device - 2018 Implementation
005110	Not Applicable	10302700000074	Solution Transfer Device	30815112020119
390301	6400	10302700000548	PROTOCO ₂ L™ Colon Insufflator	30815112020126
390302	390302	10302700000555	PROTOCO ₂ L™ Colon Insufflator Demo	30815112021130
390305	6405	10302700001859	PROTOCO ₂ L™ Accessory Cart	30815112020133
390307	390307	Not Applicable	PROTOCO ₂ L TOUCH® Colon Insufflator Demo	30815112021147
390308	390308	10302700001866	PROTOCO ₂ L TOUCH® Colon Insufflator	30815112020140
390309	390309	Not Applicable	PROTOCO ₂ L TOUCH® Administration Set With Small Catheter and Retention Cuff CO ₂ Delivery System for Colon Insufflation	30815112020157
390401	6450	10302700000562	PROTOCO ₂ L™ Administration Set With Latex Free Flexi-Cuff Retention Tip CO ₂ Delivery System for Colon Insufflation	30815112020164
390402	6470	10302700000579	PROTOCO ₂ L™ Administration Set With Small Catheter and Retention Cuff CO ₂ Delivery System for Colon Insufflation	30815112020171
390513	390513	Not Applicable	DIN 477 High Pressure Hose for CO ₂	30815112020188
450001	722	10302700000593	Mixing Container	Class 1 Medical Device - 2018 Implementation
450002	C975	10302700000609	CT Enema Administration Kit: Enema Delivery System	30815112020201
600001	EG6500	10302700000807	Fast Find Grid™ Disposable CT Biopsy Grid	30815112020218
600101	8390	10302700000814	TranSpec™ Specimen Radiography Device with Perforated Compression Plate	Class 1 Medical Device - 2018 Implementation
600102	8392	10302700000821	TranSpec™ Specimen Radiography Device with SOLID Compression Plate	Class 1 Medical Device - 2018 Implementation
600103	849	10302700000838	MammoWipe	Not Applicable
600202	N205	10302700000845	Percuguide™ LESION MARKING SYSTEM 20GAx 5CM	30815112020256
600204	N210	10302700000852	Percuguide™ LESION MARKING SYSTEM 20GAx10CM	30815112020263
600301	MB2005	10302700000869	MRI COMPATIBLE LESION MARKING SYSTEM (with wire)	30815112020270
600303	MB2010	10302700000876	MRI COMPATIBLE LESION MARKING SYSTEM (with wire)	30815112020287
600311	MR2205	10302700000890	Lufkin® MRI COMPATIBLE BIOPSY NEEDLE 22GA.x 5CM	30815112020294
600312	MR2210	10302700000906	Lufkin® MRI COMPATIBLE BIOPSY NEEDLE 22GA.x10 CM	30815112020300
600401	N105	10302700000913	PercuCut® Cut-Biopsy Needle 21GA.x 5CM	30815112020317
600402	N110	10302700000920	PercuCut® Cut-Biopsy Needle 21GA.x10CM	30815112020324
600403	N115	10302700000937	PercuCut® Cut-Biopsy Needle 21GAx15CM	30815112020331
600405	N810	10302700000944	PercuCut® Cut-Biopsy Needle 18GA.x10CM	30815112020348
600406	N815	10302700000951	PercuCut® Cut-Biopsy Needle 18GA.x15CM	30815112020355
600409	N910	10302700000968	PercuCut® Cut-Biopsy Needle 19.5Gx10CM	30815112020362

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600421	NV105	10302700000975	PercuCut [®] Self Aspirating Type Cut-Biopsy Needle 21GA.x 5CM	30815112020379
600422	NV110	10302700000982	PercuCut [®] Self Aspirating Type Cut-Biopsy Needle 21GA.x10CM	30815112020386
600423	NV115	10302700000999	PercuCut [®] Self Aspirating Type Cut-Biopsy Needle 21GA.x15CM	30815112020393
600424	NV120	10302700001002	PercuCut [®] Self Aspirating Type Cut-Biopsy Needle 21GA.x20CM	30815112020409
600429	NV915	10302700001019	PercuCut [®] Self Aspirating Type Cut-Biopsy Needle 19.5Gx15CM	30815112020416
600601	4000	10302700001064	Local Anesthesia Tray	30815112020461
600602	4100	10302700001071	Basic Biopsy Tray w/o Biopsy Needle	30815112020478
600603	4125	10302700001088	Basic Biopsy Tray w/o Biopsy Needle	30815112020485
600604	4205	10302700001095	Expanded Biopsy Tray without Biopsy Needle and Sodium Chloride	30815112020492
600701	4933	10302700001101	Hysterosalpingogram Tray	30815112020508
600802	4320	10302700001118	PercuSet [®] Myelogram Tray	30815112020515
600803	4330	10302700001125	Arthrogram Tray	30815112020522
601001	6010	10302700001132	E-Z-Gel [®] UltraSound Gel	30815112020539
601002	6015	10302700001149	E-Z-Scan [®] Low Viscosity UltraSound Gel	30815112020546
601003	6025	10302700001156	E-Z-Scan [®] Low Viscosity UltraSound Gel	30815112020553
601004	6030	10302700001163	E-Z-Gel [®] UltraSound Gel	30815112020560
710602	710602	10302700001378	Two Tank Shuttle Valve System	30815112020782
710603	710603	10302700001385	High Pressure Hose & Yoke for CO ₂	30815112020799
710604	710604	10302700001392	High Pressure Diss Hose For CO ₂	30815112020805
900302	920	10302700001460	Enema Kit: Empty Enema Bag Delivery System	30815112020812
900304	935	10302700001477	EXACTA Screw Cap Bag: Empty Enema Bag Delivery System	30815112020836
900401	848	10302700001484	Tubing Clamp: Fits Standard 5/16" Tubing	30815112020843
900402	9312	10302700001491	"Y" Connector with Tubing	30815112020850
900403	9332	10302700001507	Remote Blue Air Bulb Insufflator Air Insufflation of Colon	30815112020867
900404	9525	10302700001514	Blue Air Bulb Insufflator	30815112020874
900405	9529	10302700001521	Retention Cuff Inflator	30815112020881
901001	845	10302700001927	X-Ray Wipes	30815112020928
901003	964	10302700001545	E-Z- Mark [™]	30815112020935
901004	V390	10302700001552	Cysto-Aid [™] Urine Collection Device	30815112020942
901101	820	10302700001569	Enema Ring: Fluid Collection Device	30815112020959
901201	8816	10302700001576	Miller Enema Air Tip with Non-Latex Retention Cuff	30815112020966
901202	8825	10302700001583	Miller Enema Air Tip with Retention Cuff	30815112020973
901203	8925	10302700001590	Super XL [®] Enema System	30815112020980
901301	9501	10302700001606	Rounded Flexi-Tip [®] : Adult Enema Tip	30815112020997
901302	9503	10302700001934	XL Flexi-Tip [®] : Adult Enema Tip	30815112021000
901303	9504	10302700001613	24 Fr Infant Flexi-Tip [®] : Pediatric Enema Tip	30815112021017
901304	9507	10302700001620	Miller Enema Air Tip: Without Retention Cuff	30815112021024
901305	9514	10302700001637	14 French Pediatric Flexi-Tip [®]	30815112021031
901306	9515	10302700001644	FLEXI-STOME Cone Colostomy Tip	30815112021048
901307	9517	10302700001651	FLEXI-STOME Nipple Colonstomy Tip	30815112021055
901308	9518	10302700001668	18 French Pediatric Flexi-Tip [®]	30815112021062

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Bracco Item Number	Legacy Item Number	Legacy GTIN	Product Name	New GTIN - UDI Compliant
901309	9522	10302700001675	Junior Flexi-Tip® Pediatric Enema Tip	30815112021079
901403	C970	10302700001682	Enteroclysis Administration Kit	30815112021086
901501	ET-412	10302700001712	ENTEROCLYSIS CATHETER 13Fx155 cm	30815112021093
903101	763	10302700001781	Measuring Device For E-Z-HD™	30815112021109
903102	841	10302700001798	Flexible Straws	30815112021116
Q89072	Q89072	Not Applicable	Sani-Cloth® Plus	Not Applicable
650420	Not Applicable	Not Applicable	NEXO®	Class 1 Medical Device - 2018 Implementation
660001	Not Applicable	Not Applicable	NEXO [DOSE]™	Class 1 Medical Device - 2018 Implementation
017349	Not Applicable	10302700002115	Bracco Injengineering Transfer Set	37630039300358
640457	Not Applicable	10302700001880	Patient Set - CT Exprès™	37630039300013
640458	Not Applicable	Not Applicable	Bottle Spike Type A - CT Exprès™	37630039300006
640460	Not Applicable	10302700001903	Day Set III HP - CT Exprès™	37630039300020
651207	Not Applicable	Not Applicable	CT Exprès™ 3D Contrast Media Delivery System	47630039300096
640076	Not Applicable	Not Applicable	CT Exprès™ 3D floor Stand	37630039300143
017344	Not Applicable	10302700002009	FastLoad™ CT Syringe Pack	37630039300303
017345	Not Applicable	10302700002016	FastLoad™ CT Syringe Pack with spike	37630039300310
017347	Not Applicable	10302700001996	FastLoad™ CTA Dual Syringe Pack with spike	37630039300334
017346	Not Applicable	10302700001989	FastLoad™ CTA Dual Syringe Pack with spike	37630039300327
017348	Not Applicable	10302700002023	FastLoad™ MR Syringe Pack	37630039300297
017352	Not Applicable	10302700002030	EDA™ Patch	37630039300341
017377	Not Applicable	Not Applicable	EmpowerMR® Contrast Injector System without remote	47630039300751
016204	Not Applicable	Not Applicable	EmpowerMR® Floor Stand	37630039300402
017382	102914	Not Applicable	EmpowerMR® Penetration Panel	37630039300419
017354	102335	Not Applicable	EDA™ Module Kit	37630039300426
017285	Not Applicable	Not Applicable	EmpowerCTA®+ Injector System	47630039300430
017383	Not Applicable	Not Applicable	EmpowerCTA®+ Injector System with EDA™	47630039300447
017412	102348	Not Applicable	Power/Comm Cable (75')	37630039300501
017421	102341	Not Applicable	Interconnect Power/Comm Cable 20'	37630039300518
017523	102384 / 018221	Not Applicable	EmpowerSync® Philips Scanner Interface Adapter	37630039300549
017524	102349	Not Applicable	Empower™ Pendant Cable	37630039300570
017526	102388	Not Applicable	EmpowerSync® Remote Control Pendant Switch	37630039300587
017528	102380	Not Applicable	Empower™ IV pole	37630039300600
017416	102358	Not Applicable	Articulating arm	37630039300617
017417	102385	Not Applicable	Injector Mounting Arm, Left	37630039300624
017418	102386	Not Applicable	Injector Mounting Arm, Right	37630039300631
017419	102393	Not Applicable	Ceiling Mount Adapter Plate	37630039300648
017413	102355	Not Applicable	Ceiling Column Long	37630039300655
017414	102356	Not Applicable	Ceiling Column Medium	37630039300662
017415	102357	Not Applicable	Ceiling Column Short	37630039300679
015781	102351	Not Applicable	EDA™ Clip	37630039300686
017410	Not Applicable	Not Applicable	Floor Stand	37630039300693
017411	Not Applicable	Not Applicable	Floor Stand Shroud	37630039300709
014623	Not Applicable	Not Applicable	CPT2000 Single Use Manifold Kit	http://www.acist.com/UDI
014212	Not Applicable	10302700000098	STD. HAND CONTROL 54" AT-S54	http://www.acist.com/UDI

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014612	Not Applicable	10302700000104	SYRINGE KIT A 2000 10/CS ACIST	http://www.acist.com/UDI .
014613	Not Applicable	10302700000111	MANIFOLD KIT BT 2000 10/CS ACIST	http://www.acist.com/UDI .
014621	Not Applicable	10302700000128	ACIST [®] MANIFOLD KIT - B2000	http://www.acist.com/UDI .
014647	Not Applicable	10302700000159	ENDOVASC HAND CONTROLLER	http://www.acist.com/UDI .
014644	Not Applicable	10302700000142	AngioTouch [®] KIT AT-P54 ACIST	http://www.acist.com/UDI .
014113	Not Applicable	10302700000081	A2000v Multiuse Syringe Kit	http://www.acist.com/UDI .
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