

	Dokumentas#	RTP-WK-T3010
	Peržiūra#	16A
	Išleidimo data:	Žr. peržiūros istoriją
Puslapis 1 iš 10		

EB ATITIKTIES DEKLARACIJA

Teisinis gamintojo pavadinimas ir adresas:	Teleflex Medical 3015 Carrington Mill Blvd. Morrisville NC, 27560. JAV
Įgaliotojo atstovo pavadinimas ir adresas:	Teleflex Medical IDA Business and Technology Park Dublin Road Athlone, Co. Westmeath, Airija
Notifikuotosios įstaigos pavadinimas ir adreas:	X 1 klasė: netaikoma Is, Im, IIa, IIb, III klasė

X 1 klasė

„Teleflex Medical“ pareiškia, kad gaminiai atitinka Tarybos direktyvos 93/42/EEB, 1993 m. Birželio mėn 14 d. Su pakeitimais, padarytais 2007/47/EB, ir atitinka VII priedą ir BSI BS EN ISO 13485: 2016, kuriuos įgyvendino Europos Sąjungos medicinos prietaisų reglamentai.

Is, Im, IIa, IIb, III klasė

„Teleflex Medical“ pareiškia, kad gaminiai atitinka Tarybos direktyvos 93/42/EEB, 1993 m. Birželio mėn, 14 d. Su pakeitimais, padarytais 2007/47/EB, ir atitinka priedą. Įterpti priedo numerį ir įterpti versiją (ISO, BSI BS EN ISO ir kt.) ISO 13485: Įterpti paskelbimo datą, įgyvendintą Europos Sąjungos medicinos prietaisų reglamentuose, patvirtintuose anksčiau išvardyta notifikuotoji įstaiga:

„Teleflex Medical“ patvirtina, kad kitai notifikuotajai įstaigai nebuvo pateikta jokia kita paraiška dėl tų pačių prietaisų kokybės valdymo sistemos.

„Teleflex Medical“ sutinka sukurti, įdiegti ir prižiūrėti oficialiai pripažintą kokybės valdymo sistemą, kad būtų užtikrintas tinkamumas ir veiksmingumas.

„Teleflex Medical“ sutinka kurti, įgyvendinti ir prižiūrėti dokumentais pagrįstą patirties stebėjimo procesą po gamybos, įskaitant pranešimą apie įvykius, apie kuriuos reikia pranešti pagal Europos medicinos prietaisų budrumo sistemos gaires.

„Teleflex Medical“ patvirtina, kad jokie vaistiniai preparatai/vaistai nėra įtraukti į jokių prietaisų, kuriems taikomas prietaisų planas.

„Teleflex Medical“ sutinka informuoti paskirtąjį notifikuotąjį įstaigą apie bet kokius planuojamus ar neplanuotus esminius kokybės pokyčius valdymo sistemoje.

Produkto pavadinimas	Metalinio ligavimo sistemos kabučių aplikatoriai ir kabučių nuėmėjai
Klasifikacija:	Klasė 1, Taisyklė 6
EB Sertifikatai Nr.	Kanadietiški: ISO 13485:2016 – US18/81827522 (MDSAP) Europietiški - ISO 13485: 2016 / BS EN ISO 13485: 2016 - US97 / 10878
Atitikties vertinimo būdai:	MDD (93/42 / EEB) VII priedas, EB deklaracija



Dokumentas#	RTP-WK-T3010
Peržiūra#	16A
Išleidimo data:	Žr. peržiūros istoriją

Puslapis 2 iš 10

Produkto kodas:	Produkto aprašymas	CE išplatavimo data	GMPN kodas
Weck Horizon / Hemoclip Metal Clips			
114527	Hemodip Plus EndoTouch Applier, Medium-Large, 25° Angled, 13"	2010-03	35798
137061	Horizon Applier, Small, Curved, 6"	2010-03	35798
137062	Horizon Applier, Small-Wide, Curved, 6"	2010-03	35798
137081	Horizon Applier, Small, Curved, 8"	2010-03	35798
137082	Horizon Applier Small-Wide, Curved, 8"	2010-03	35798
137085	Horizon Applier, Small, Angled, 8"	2010-03	35798
137086	Horizon Applier, Small-Wide, Angled, 8"	2010-03	35798
137111	Horizon Applier, Small, Curved, 11"	2010-03	35798
137112	Horizon Applier, Small-Wide, Curved, 11"	2010-03	35798
137117	Horizon Multi-Angle Applier, Small-Wide, 45° Angle, 11"	2010-03	35798
137118	Horizon Multi-Angle Applier, Small-Wide, Curved, 11"	2010-03	35798
237061	Horizon Applier, Medium, Curved, 6"	2010-03	35798
237081	Horizon Applier, Medium, Curved, 8"	2010-03	35798
237085	Horizon Applier, Medium, Angled, 8"	2010-03	35798
237111	Horizon Applier, Medium, Curved, 11"	2010-03	35798
237115	Horizon Applier, Medium, Angled, 11"	2010-03	35798
237117	Horizon Applier, Medium, Right Angle, 11"	2010-03	35798
237141	Horizon Applier, Medium, 20° Curved, 14"	2010-03	35798
237145	Horizon Applier, Medium, 55° Angled, 14"	2010-03	35798
238110	Horizon Endoscopic Applier, Medium, 10mm, 11"	2010-03	35798
238170	Horizon Endoscopic Applier, Medium, 10mm, 18"	2010-03	35798
337081	Horizon Applier, Medium-Large, Curved, 8"	2010-03	35798
337085	Horizon Applier, Medium-Large, Angled, 8"	2010-03	35798
337111	Horizon Applier, Medium-Large, Curved, 11"	2010-03	35798
337115	Horizon Applier, Medium-Large, Angled, 11"	2010-03	35798
337117	Horizon Applier, Medium-Large, Right Angle, 11"	2010-03	35798
337141	Horizon Applier, Medium-Large, 20° Curved, 14"	2010-03	35798
337145	Horizon Applier, Medium-Large, 55° Angled, 14"	2010-03	35798
338110	Horizon Endoscopic Applier, Medium-Large, 10mm, 11"	2010-03	35798
338170	Horizon Endoscopic Applier, Medium-Large, 10mm, 18"	2010-03	35798
437081	Horizon Applier, Large, Curved, 8"	2010-03	35798
437085	Horizon Applier, Large, Angled, 8"	2010-03	35798
437111	Horizon Applier, Large, Curved, 11"	2010-03	35798
437115	Horizon Applier, Large, Angled, 11"	2010-03	35798
437117	Horizon Applier, Large, Right Angle, 11"	2010-03	35798
437141	Horizon Applier, Large, 20° Curved, 14"	2010-03	35798
437145	Horizon Applier, Large, 55° Angle, 14"	2010-03	35798
438110	Horizon Endoscopic Clip Applier, Large, 12mm, 11"	2010-03	35798
438170	Horizon Endoscopic Clip Applier, Large, 12mm, 18"	2010-03	35798
523105	Hemodip Traditional Applier, Medium, Right Angle, 8"	2010-03	35798
523106	Hemodip Traditional Applier, Medium, Right Angle, 11"	2010-03	35798
523109	Hemodip Traditional Applier, Medium, Curved, 6"	2010-03	35798
523110	Hemodip Traditional Applier, Medium, Curved, 8"	2010-03	35798
523111	Hemodip Traditional Applier, Medium, Curved, 11"	2010-03	35798
523120	Weck Metal Clip Removing Forceps, Straight, 6"	2010-03	10895
523121	Weck Metal Clip Removing Forceps, Angled Shanks, 10"	2010-03	10895
523130	Weck Metal Ligating Clip Cartridge Base, 7"	2010-03	58050
523140	Hemodip Traditional Applier, Small, Curved, 6"	2010-03	35798
523150	Hemodip Traditional Applier, Small, Curved, 8"	2010-03	35798
523151	Hemodip Traditional Applier, Small, Curved, 11"	2010-03	35798

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Document #: FRM-00751	Revision#: 00	Issue Date: See Agile	Parent Document: WF003907
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Dokumentas#	RTP-WK-T3010
Peržiūra#	16A
Išleidimo data:	Žr. peržiūros istoriją
Puslapis 3 iš 10	

523165	Hemoclip Traditional Applier, Medium-Large, Curved, 8"	2010-03	35798
523166	Hemoclip Traditional Applier, Medium-Large, Curved, 11"	2010-03	35798
523167	Hemoclip Traditional Applier, Medium-Large, Right Angle, 8"	2010-03	35798
523168	Hemoclip Traditional Applier, Medium-Large, Right Angle, 11"	2010-03	35798
523175	Hemoclip Traditional Applier, Large, Curved, 8"	2010-03	35798
523177	Hemoclip Traditional Applier, Large, Right Angle, 8"	2010-03	35798
523178	Hemoclip Traditional Applier, Large, Right Angle, 11"	2010-03	35798
523180	Hemoclip Traditional Applier, Large, Curved, 11"	2010-03	35798
523540	Hemoclip Traditional Precision Applier, Small, Curved, 6"	2010-03	35798
523550	Hemoclip Traditional Precision Applier, Small, Curved, 8"	2010-03	35798
523551	Hemoclip Traditional Precision Applier, Small, Curved, 11"	2010-03	35798
533105	Hemoclip Plus Applier, Medium, Right Angle, 8"	2010-03	35798
533106	Hemoclip Plus Applier, Medium, Right Angle, 11"	2010-03	35798
533108	Hemoclip Plus Applier, Medium, 45° Angle, 11"	2010-03	35798
533109	Hemoclip Plus Applier, Medium, Curved, 6"	2010-03	35798
533110	Hemoclip Plus Applier, Medium, Curved, 8"	2010-03	35798
533111	Hemoclip Plus Applier, Medium, Curved, 11"	2010-03	35798
533140	Hemoclip Plus Applier, Small, Curved, 6"	2010-03	35798
533150	Hemoclip Plus Applier, Small, Curved, 8"	2010-03	35798
533151	Hemoclip Plus Applier, Small, Curved, 11"	2010-03	35798
533152	Hemoclip Plus Applier, Small, Right Angle, 6"	2010-03	35798
533164	Hemoclip Plus Applier, Medium-Large, 45° Angle, 11"	2010-03	35798
533165	Hemoclip Plus Applier, Medium-Large, Curved, 8"	2010-03	35798
533166	Hemoclip Plus Applier, Medium-Large, Curved, 11"	2010-03	35798
533167	Hemoclip Plus Applier, Medium-Large, Right Angle, 8"	2010-03	35798
533168	Hemoclip Plus Applier, Medium-Large, Right Angle, 11"	2010-03	35798
533175	Hemoclip Plus Applier, Large, Curved, 8"	2010-03	35798
533177	Hemoclip Plus Applier, Large, Right Angle, 8"	2010-03	35798
533178	Hemoclip Plus Applier, Large, Right Angle, 11"	2010-03	35798
533180	Hemoclip Plus Applier, Large, Curved, 11"	2010-03	35798
533181	Hemoclip Plus Applier, Large, 45° Angle, 11"	2010-03	35798
534140	Hemoclip Plus Applier Small Strongpoint, Curved, 6"	2010-03	35798
534150	Hemoclip Plus Applier Small Strongpoint, Curved, 8"	2010-03	35798
534151	Hemoclip Plus Applier Small Strongpoint, Curved, 11"	2010-03	35798
537061	Horizon Applier, Micro, Curved, 6"	2010-03	35798
537081	Horizon Applier, Micro, Curved, 8"	2010-03	35798
237115DR	Horizon Applier, Medium, Angled, Double-Ring Coat, 11"	2010-03	35798
238110T	Horizon Take-Apart Endoscopic Clip Applier, Medium	2010-03	35798
337115DR	Horizon Applier, Medium-Large, Angled, Double-Ring Coat, 11"	2010-03	35798
337117DR	Horizon Applier, Medium-Large, Right Angle, Double-Ring Coat, 11"	2010-03	35798
338110T	Horizon Take-Apart Endoscopic Applier, Medium-Large	2010-03	35798
437111DR	Horizon Applier, Large, Curved, Double-Ring Coat, 11"	2010-03	35798
437115DR	Horizon Applier, Large, Angled, Double-Ring Coat, 11"	2010-03	35798
437117DR	Horizon Applier, Large, Right Angle, Double-Ring Coat, 11"	2010-03	35798
238200	Horizon Endo Saphenous Vein (ESV) Applier, Medium, 13"	2011-02	35798
137062DR	Horizon Applier, Small-Wide, Curved, Double-Ring Coat, 6"	2010-03	35798
137062DR	Horizon Applier Small-Wide, Curved, Double-Ring Coat, 8"	2010-03	35798
237081DR	Horizon Applier, Medium, Curved, Double-Ring Coat, 8"	2010-03	35798
237111DR	Horizon Applier, Medium, Curved, Double-Ring Coat, 11"	2010-03	35798
237117DR	Horizon Applier, Medium, Right Angle, Double Ring Coat, 11"	2010-03	35798
337081DR	Horizon Applier, Medium-Large, Curved, Double-Ring Coat, 8"	2010-03	35798
337111DR	Horizon Applier, Medium-Large, Curved, Double-Ring Coat, 11"	2010-03	35798
137061R	Horizon Applier, Small, Curved, 6", Refurbished	2012-06	35798
137062R	Horizon Applier, Small-Wide, Curved, 6", Refurbished	2012-06	35798
137081R	Horizon Applier, Small, Curved, 8", Refurbished	2012-06	35798
137082R	Horizon Applier Small-Wide, Curved, 6", Refurbished	2012-06	35798

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Document #: FHM-000 T31	Revision#: 00	Issue Date: See Agile	Parent Document: WI-00390T
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Dokumentas#

RTP-WK-T3010

Peržiūra#

16A

Išleidimo data:

Žr. peržiūros istoriją

Puslapis 4 iš 10

137085R	Horizon Applier, Small, Angled, 8°, Refurbished	2012-06	35798
137086R	Horizon Applier, Small-Wide, Angled, 8°, Refurbished	2012-06	35798
137111R	Horizon Applier, Small, Curved, 11°, Refurbished	2012-06	35798
137112R	Horizon Applier, Small-Wide, Curved, 11°	2012-06	35798
237061R	Horizon Applier, Medium, Curved, 6°, Refurbished	2012-06	35798
237081R	Horizon Applier, Medium, Curved, 8°, Refurbished	2012-06	35798
237085R	Horizon Applier, Medium, Angled, 8°, Refurbished	2012-06	35798
237111R	Horizon Applier, Medium, Curved, 11°, Refurbished	2012-06	35798
237115R	Horizon Applier, Medium, Angled, 11°, Refurbished	2012-06	35798
337081R	Horizon Applier, Medium-Large, Curved, 8°, Refurbished	2012-06	35798
337085R	Horizon Applier, Medium-Large, Angled, 8°, Refurbished	2012-06	35798
337111R	Horizon Applier, Medium-Large, Curved, 11°, Refurbished	2012-06	35798
337115R	Horizon Applier, Medium-Large, Angled, 11°, Refurbished	2012-06	35798
337117R	Horizon Applier, Medium-Large, Right Angle, 11°	2012-06	35798
437081R	Horizon Applier, Large, Curved, 8°, Refurbished	2012-06	35798
437085R	Horizon Applier, Large, Angled, 8°, Refurbished	2012-06	35798
437111R	Horizon Applier, Large, Curved, 11°, Refurbished	2012-06	35798
437115R	Horizon Applier, Large, Angled, 11°, Refurbished	2012-06	35798
437117R	Horizon Applier, Large, Right Angle, 11°, Refurbished	2012-06	35798
137117R	Horizon Multi-Angle Applier, Small-Wide, 45° Angle, 11°, Refurbished	2012-06	35798
137118R	Horizon Multi-Angle Applier, Small-Wide, Curved, 11°, Refurbished	2012-06	35798
237117R	Horizon Applier, Medium, Right Angle, 11°, Refurbished	2012-06	35798
237141R	Horizon Applier, Medium, 20° Curved, 14°, Refurbished	2012-06	35798
237145R	Horizon Applier, Medium, 55° Angled, 14°, Refurbished	2012-06	35798
337141R	Horizon Applier, Medium-Large, 20° Curved, 14°, Refurbished	2012-06	35798
337145R	Horizon Applier, Medium-Large, 55° Angled, 14°, Refurbished	2012-06	35798
437141R	Horizon Applier, Large, 20° Curved, 14°, Refurbished	2012-06	35798
437145R	Horizon Applier, Large, 55° Angle, 14°, Refurbished	2012-06	35798
537061R	Horizon Applier, Micro, Curved, 6°, Refurbished	2012-06	35798
537081R	Horizon Applier, Micro, Curved, 8°, Refurbished	2012-06	35798
523105R	Hemoclip Traditional Applier, Medium, Right Angle, 8°, Refurbished	2012-06	35798
523106R	Hemoclip Traditional Applier, Medium, Right Angle, 11°, Refurbished	2012-06	35798
523109R	Hemoclip Traditional Applier, Medium, Curved, 6°, Refurbished	2012-06	35798
523110R	Hemoclip Traditional Applier, Medium, Curved, 8°	2012-06	35798
523111R	Hemoclip Traditional Applier, Medium, Curved, 11°, Refurbished	2012-06	35798
523140R	Hemoclip Traditional Applier, Small, Curved, 6°, Refurbished	2012-06	35798
523150R	Hemoclip Traditional Applier, Small, Curved, 8°, Refurbished	2012-06	35798
523151R	Hemoclip Traditional Applier, Small, Curved, 11°, Refurbished	2012-06	35798
523165R	Hemoclip Traditional Applier, Medium-Large, Curved, 8°, Refurbished	2012-06	35798
523166R	Hemoclip Traditional Applier, Medium-Large, Curved, 11°, Refurbished	2012-06	35798
523167R	Hemoclip Traditional Applier, Medium-Large, Right Angle, 8°, Refurbished	2012-06	35798
523168R	Hemoclip Traditional Applier, Medium-Large, Right Angle, 11°, Refurbished	2012-06	35798
523175R	Hemoclip Traditional Applier, Large, Curved, 8°, Refurbished	2012-06	35798
523177R	Hemoclip Traditional Applier, Large, Right Angle, 8°, Refurbished	2012-06	35798
523178R	Hemoclip Traditional Applier, Large, Right Angle, 11°, Refurbished	2012-06	35798
523180R	Hemoclip Traditional Applier, Large, Curved, 11°, Refurbished	2012-06	35798
523540R	Hemoclip Traditional Precision Applier, Small, Curved, 6°, Refurbished	2012-06	35798
523550R	Hemoclip Traditional Precision Applier, Small, Curved, 8°, Refurbished	2012-06	35798
523551R	Hemoclip Traditional Precision Applier, Small, Curved, 11°, Refurbished	2012-06	35798
523120R	Weck Metal Clip Removing Forceps, Straight, 6°, Refurbished	2012-06	10895
523121R	Weck Metal Clip Removing Forceps, Angled Shanks, 10°, Refurbished	2012-06	10895
523130R	Weck Metal Ligating Clip Cartridge Base, 7°, Refurbished	2012-06	58050
533105R	Hemoclip Plus Applier, Medium, Right Angle, 8°, Refurbished	2012-06	35798
533106R	Hemoclip Plus Applier, Medium, Right Angle, 11°, Refurbished	2012-06	35798
533108R	Hemoclip Plus Applier, Medium, 45° Angle, 11°, Refurbished	2012-06	35798
533109R	Hemoclip Plus Applier, Medium, Curved, 6°, Refurbished	2012-06	35798

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Document #: FRM-000751 Revision #: 00 Issue Date: See Agile Parent Document: WI-003907



Dokumentas#	RTP-WK-T3010
Peržiūra#	16A
Išleidimo data:	Žr. peržiūros istoriją

Puslapis 5 iš 10

533110R	Hemoclip Plus Applier, Medium, Curved, 8°, Refurbished	2012-06	35798
533111R	Hemoclip Plus Applier, Medium, Curved, 11°, Refurbished	2012-06	35798
533140R	Hemoclip Plus Applier, Small, Curved, 6°, Refurbished	2012-06	35798
533150R	Hemoclip Plus Applier, Small, Curved, 8°, Refurbished	2012-06	35798
533151R	Hemoclip Plus Applier, Small, Curved, 11°, Refurbished	2012-06	35798
533152R	Hemoclip Plus Applier, Small, Right Angle, 8°, Refurbished	2012-06	35798
533164R	Hemoclip Plus Applier, Medium-Large, 45° Angle, 11°, Refurbished	2012-06	35798
533165R	Hemoclip Plus Applier, Medium-Large, Curved, 8°, Refurbished	2012-06	35798
533166R	Hemoclip Plus Applier, Medium-Large, Curved, 11°, Refurbished	2012-06	35798
533167R	Hemoclip Plus Applier, Medium-Large, Right Angle, 8°, Refurbished	2012-06	35798
533168R	Hemoclip Plus Applier, Medium-Large, Right Angle, 11°, Refurbished	2012-06	35798
533175R	Hemoclip Plus Applier, Large, Curved, 8°, Refurbished	2012-06	35798
533177R	Hemoclip Plus Applier, Large, Right Angle, 8°, Refurbished	2012-06	35798
533178R	Hemoclip Plus Applier, Large, Right Angle, 11°, Refurbished	2012-06	35798
533180R	Hemoclip Plus Applier, Large, Curved, 11°, Refurbished	2012-06	35798
533181R	Hemoclip Plus Applier, Large, 45° Angle, 11°, Refurbished	2012-06	35798
534140R	Hemoclip Plus Applier Small Strongpoint, Curved, 6°, Refurbished	2012-06	35798
534150R	Hemoclip Plus Applier Small Strongpoint, Curved, 8°, Refurbished	2012-06	35798
70010	Vesoclude Remover CVD 11°	2020-01	35649
70060	Vesoclude Remover STRAIGHT 8°	2020-01	35649
70212	Vesoclude Applier SMALL CVD 11°	2020-01	35649
70212L	Vesoclude Applier SMALL CVD 11°	2020-01	35649
70262	Vesoclude Applier SMALL CVD 6° 152MM	2020-01	35649
70282	Vesoclude Applier SMALL CVD 8° 203MM	2020-01	35649
70282L	Vesoclude Applier SMALL CVD 8°	2020-01	35649
70285	Vesoclude Applier SMALL 55° ANG 8°	2020-01	35649
70285L	Vesoclude Applier SMALL 55° ANG 8°	2020-01	35649
70312	Vesoclude Applier SW CVD 11° 280MM	2020-01	35649
70362	Vesoclude Applier SW CVD 6° 152MM	2020-01	35649
70382	Vesoclude Applier SW CVD 8°	2020-01	35649
70385	Vesoclude Applier SW 55° ANG 8°	2020-01	35649
70412	Vesoclude Applier MED CVD 11° 280MM	2020-01	35649
70415	Vesoclude Applier MED 55° ANG 280MM	2020-01	35649
70417	Vesoclude Applier MED 70° ANG 280MM	2020-01	35649
70462	Vesoclude Applier MED CVD 8° 152MM	2020-01	35649
70482	Vesoclude Applier MED CVD 8° 203MM	2020-01	35649
70485	Vesoclude Applier MED 55° ANG 8° 203MM	2020-01	35649
70512	Vesoclude Applier ML CVD 11° 280MM	2020-01	35649
70515	Vesoclude Applier ML 55° ANG 11° 280MM	2020-01	35649
70582	Vesoclude Applier ML CVD 8° 203MM	2020-01	35649
70585	Vesoclude Applier ML 55° ANG ML 8° 203MM	2020-01	35649
70612	Vesoclude Applier L CVD 11° 280MM	2020-01	35649
70615	Vesoclude Applier L 55° ANG 11° 280MM	2020-01	35649
70617	Vesoclude Applier L 70° ANG 11°	2020-01	35649
70682	Vesoclude Applier L CVD 8° 203MM	2020-01	35649
70685	Vesoclude Applier L 55° ANG 8°	2020-01	35649
80402X	Vesoclude Applier MED Endo CVD 13° 33CM	2020-01	35649
80502X	Vesoclude Applier ML Endo CVD 13° 280MM	2020-01	35649
80602	Vesoclude Applier L Endo CVD 11°	2020-01	35649
90502	Vesoclude APLR ML Endo ID 10/11MM L 18° 457MM	2020-01	35649
90602	Vesoclude APLR ML Endo ID 12MM L 18° 457MM	2020-01	35649

* Indicates the item is within the scope of and in compliance with European Directive 2011/65/EU, The Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment

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Document #: FRM-000791	Revision#: 00	Issue Date: See Agile	Parent Document: WI-003907
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	Dokumentas#	RTP-WK-T3010
	Peržiūra#	16A
	Išleidimo data:	Žr. peržiūros istoriją
Puslapis 6 iš 10		

Tvirtintojo vardas ir pareigos:	Kim Campbell RA medicininės komandos vadovas
Tvirtintojo parašas:	
Patvirtinimo data:	2020 m. gegužės mėn. 5 d.
Patvirtinimo vieta:	Teleflex Medical 3015 Carrington Mill Blvd. Morrisville NC, 27560 JAV

Kanadietiškas klasifikavimas

Žemiau išvardinti prietaisai atitinka kanadietiškus reikalavimus:

Device	Canadian License #	Issue Date	Class of Product
5331 05	87 334	20 11-10-05	2
5331 06	87 334	20 11-10-05	2
5331 08	87 334	20 11-10-05	2
5331 09	87 334	20 11-10-05	2
5331 10	87 334	20 11-10-05	2
5331 11	87 334	20 11-10-05	2
5331 40	87 334	20 11-10-05	2
5331 50	87 334	20 11-10-05	2
5331 51	87 334	20 11-10-05	2
5331 52	87 334	20 11-10-05	2
5331 64	87 334	20 11-10-05	2
5331 65	87 334	20 11-10-05	2
5331 66	87 334	20 11-10-05	2
5331 67	87 334	20 11-10-05	2
5331 68	87 334	20 11-10-05	2
5331 75	87 334	20 11-10-05	2
5331 77	87 334	20 11-10-05	2
5331 78	87 334	20 11-10-05	2
5331 80	87 334	20 11-10-05	2
5331 81	87 334	20 11-10-05	2
5341 40	87 334	20 11-10-05	2
5341 50	87 334	20 11-10-05	2
5341 51	87 334	20 11-10-05	2
5331 05R	87 334	20 12-07-06	2
5331 06R	87 334	20 12-07-06	2
5331 08R	87 334	20 12-07-06	2
5331 09R	87 334	20 12-07-06	2
5331 10R	87 334	20 12-07-06	2
5331 11R	87 334	20 12-07-06	2
5331 40R	87 334	20 12-07-06	2
5331 50R	87 334	20 12-07-06	2
5331 51R	87 334	20 12-07-06	2
5331 52R	87 334	20 12-07-06	2
5331 64R	87 334	20 12-07-06	2
5331 65R	87 334	20 12-07-06	2
5331 66R	87 334	20 12-07-06	2
5331 67R	87 334	20 12-07-06	2

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Dokumentas#	RTP-WK-T3010
Peržiūra#	16A
Išleidimo data:	Žr. peržiūros istoriją

Puslapis 7 iš 10

533168R	87334	2012-07-06	2
533175R	87334	2012-07-06	2
533177R	87334	2012-07-06	2
533178R	87334	2012-07-06	2
137061R	87334	2012-07-06	2
137062R	87334	2012-07-06	2
137081R	87334	2012-07-06	2
137082R	87334	2012-07-06	2
137085R	87334	2012-07-06	2
137086R	87334	2012-07-06	2
137111R	87334	2012-07-06	2
137112R	87334	2012-07-06	2
137117R	87334	2012-07-06	2
137118R	87334	2012-07-06	2
237061R	87334	2012-07-06	2
237081R	87334	2012-07-06	2
237085R	87334	2012-07-06	2
237111R	87334	2012-07-06	2
237115R	87334	2012-07-06	2
237117R	87334	2012-07-06	2
237141R	87334	2012-07-06	2
237145R	87334	2012-07-06	2
337081R	87334	2012-07-06	2
337085R	87334	2012-07-06	2
337111R	87334	2012-07-06	2
337115R	87334	2012-07-06	2
337117R	87334	2012-07-06	2
337141R	87334	2012-07-06	2
337145R	87334	2012-07-06	2
437081R	87334	2012-07-06	2
437085R	87334	2012-07-06	2
437111R	87334	2012-07-06	2
437115R	87334	2012-07-06	2
437117R	87334	2012-07-06	2
437141R	87334	2012-07-06	2
437145R	87334	2012-07-06	2
537061R	87334	2012-07-06	2
537081R	87334	2012-07-06	2
114527	87334	2012-03-14	2
137061	87334	2012-04-16	2
137062	87334	2012-04-16	2
137062DR	87334	2012-04-16	2
137081	87334	2012-04-16	2
137082	87334	2012-04-16	2
137082DR	87334	2012-04-16	2
137085	87334	2012-04-16	2
137086	87334	2012-04-16	2
137111	87334	2012-04-16	2
137112	87334	2012-04-16	2
137117	87334	2012-04-16	2
137118	87334	2012-04-16	2
237061	87334	2012-04-16	2
237081	87334	2012-04-16	2
237081DR	87334	2012-04-16	2
237085	87334	2012-04-16	2
237111	87334	2012-04-16	2

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	Dokumentas#	RTP-WK-T3010
	Peržiūra#	16A
	Išleidimo data:	Žr. peržiūros istoriją
Puslapis 8 iš 10		

237111DR	87334	2012-04-16	2
237115	87334	2012-04-16	2
237115DR	87334	2012-04-16	2
237117	87334	2012-04-16	2
237117DR	87334	2012-04-16	2
237141	87334	2012-04-16	2
237145	87334	2012-04-16	2
238110	87334	2012-04-16	2
238110T	87334	2012-04-16	2
238170	87334	2012-04-16	2
238200	87334	2012-04-16	2
337081	87334	2012-04-16	2
337081DR	87334	2012-04-16	2
337085	87334	2012-04-16	2
337111	87334	2012-04-16	2
337111DR	87334	2012-04-16	2
337115	87334	2012-04-16	2
337115DR	87334	2012-04-16	2
337117	87334	2012-04-16	2
337117DR	87334	2012-04-16	2
337141	87334	2012-04-16	2
337145	87334	2012-04-16	2
338110	87334	2012-04-16	2
338110T	87334	2012-04-16	2
338170	87334	2012-04-16	2
437081	87334	2012-04-16	2
437111	87334	2012-04-16	2
437111DR	87334	2012-04-16	2
437115	87334	2012-04-16	2
437115DR	87334	2012-04-16	2
437117	87334	2012-04-16	2
437117DR	87334	2012-04-16	2
437141	87334	2012-04-16	2
437145	87334	2012-04-16	2
438110	87334	2012-04-16	2
438170	87334	2012-04-16	2
537061	87334	2012-04-16	2
537081	87334	2012-04-16	2
437085	87334	2012-04-16	2
523105	87334	2012-04-16	2
523106	87334	2012-04-16	2
523109	87334	2012-04-16	2
523110	87334	2012-04-16	2
523111	87334	2012-04-16	2
523120	87334	2012-04-16	2
523121	87334	2012-04-16	2
523140	87334	2012-04-16	2
523150	87334	2012-04-16	2
523151	87334	2012-04-16	2
523165	87334	2012-04-16	2
523166	87334	2012-04-16	2
523167	87334	2012-04-16	2
523168	87334	2012-04-16	2
523175	87334	2012-04-16	2
523177	87334	2012-04-16	2
523178	87334	2012-04-16	2

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Dokumentas#	RTP-WK-T3010
Peržiūra#	16A
Išleidimo data:	Žr. peržiūros istoriją

Puslapis 9 iš 10

5231 80	87 334	2012-04-16	2
5235 40	87 334	2012-04-16	2
5235 50	87 334	2012-04-16	2
5235 51	87 334	2012-04-16	2
5231 06R	87 334	2012-07-06	2
5231 06R	87 334	2012-07-06	2
5231 09R	87 334	2012-07-06	2
5231 10R	87 334	2012-07-06	2
5231 11R	87 334	2012-07-06	2
5231 40R	87 334	2012-07-06	2
5231 50R	87 334	2012-07-06	2
5231 51R	87 334	2012-07-06	2
5231 65R	87 334	2012-07-06	2
5231 66R	87 334	2012-07-06	2
5231 67R	87 334	2012-07-06	2
5231 68R	87 334	2012-07-06	2
5231 75R	87 334	2012-07-06	2
5231 77R	87 334	2012-07-06	2
5231 78R	87 334	2012-07-06	2
5231 80R	87 334	2012-07-06	2
5235 40R	87 334	2012-07-06	2
5235 50R	87 334	2012-07-06	2
5235 51R	87 334	2012-07-06	2
5231 20R	87 334	2012-07-06	2
5231 21R	87 334	2012-07-06	2
5331 80R	87 334	2012-07-06	2
5331 81R	87 334	2012-07-06	2
5341 40R	87 334	2012-07-06	2
5341 50R	87 334	2012-07-06	2
7021 2	94160	11/3/2014	2
7021 2L	94160	11/3/2014	2
7026 2	94160	11/3/2014	2
7028 2	94160	11/3/2014	2
7028 2L	94160	11/3/2014	2
7028 5	94160	11/3/2014	2
7031 2	94160	11/3/2014	2
7036 2	94160	11/3/2014	2
7038 2	94160	11/3/2014	2
7038 5	94160	11/3/2014	2
7041 2	94160	11/3/2014	2
7041 5	94160	11/3/2014	2
7041 7	94160	11/3/2014	2
7046 2	94160	11/3/2014	2
7048 2	94160	11/3/2014	2
7048 5	94160	11/3/2014	2
7051 2	94160	11/3/2014	2
7051 5	94160	11/3/2014	2
7058 2	94160	11/3/2014	2
7058 5	94160	11/3/2014	2
7061 2	94160	11/3/2014	2
7061 5	94160	11/3/2014	2
7061 7	94160	11/3/2014	2
7068 2	94160	11/3/2014	2
7068 5	94160	11/3/2014	2

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Document #: FRM-000 751	Revision#: 00	Issue Date: See Agile	Parent Document: WI-003907
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	Dokumentas#	RTP-WK-T3010
	Peržiūra#	16A
	Išleidimo data:	Žr. peržiūros istoriją
Puslapis 10 iš 10		

80402X	94160	6/18/2018	2
80502X	94160	6/18/2018	2
80602	94160	6/18/2018	2
90502	94160	6/18/2018	2
90602	94160	6/18/2018	2

Produkto aprašymas	<p>Suprojektuoti „Weck“ ir „Vesocclude“ kabučių aplikatoriai ir nuėmėjai skirti naudoti atliekant atviras ir endoskopines chirurgines procedūras, kai „Weck“ ir „Vesocclude“ kabutės yra taikomos. Aplikatoriai ir nuėmėjai gaminami iš nerūdijančio plieno, kurie leidžia ilgaamžiškumą, perdirbimą ir pakartotinį naudojimą.</p> <p>Kabučių aplikatoriai yra valdomi rankiniu būdu ir vienu metu pateikia vieną kabutę.</p>
Naudojimo indikacijos	<p>„Weck“ ir „Vesocclude“ kabučių aplikatoriai yra skirti naudoti kaip „Weck“ metalinių susegimo spaustukų pristatymo įtaisai. Kitų gamintojų kabutės negali būti naudojami su šiais prietaisais.</p> <p>„Weck“ ir „Vesocclude“ kabučių nuėmėjai skirta pašalinti visas „Weck“ kabutes panaudotas per atviras procedūras.</p>
Paskirtis	<p>„Weck“ ir „Vesocclude“ kabučių aplikatoriai yra skirti naudoti kaip „Weck“ metalinių susegimo spaustukų pristatymo įtaisai. Kitų gamintojų kabutės negali būti naudojami su šiais prietaisais.</p> <p>„Weck“ ir „Vesocclude“ kabučių nuėmėjai skirta pašalinti visas „Weck“ kabutes panaudotas per atviras procedūras.</p>
Kontraindikacijos	<p>„Weck“ ir „Vesocclude“ ligavimo kabutės nėra skirtos naudoti kaip kontraceptinis kiaušintakių susegėjas.</p> <p>"Weck" ir "Vesocclude" ligavimo kabutes yra draudžiama naudoti inkstų arterijos perrišimams, laparoskopinių donorų nefrektomijų metu.</p>
Gamintojas	<p>Weck ligavimo aplikatoriai ir nuėmėjai Tecomet Inc. 5307 95th Ave. Kenosha, WI 53144</p>

	<p>JAV Weck ligavimo aplikatoriai ir nuėmėjai Koscher & Wuertz Einsteinstrasse 7, Spalchingen, DE-BW Vokietija 78549</p> <p>Vesoclude ligavimo apikatoriai Trimed LLC 9310 Focal Point Raleigh, NC 27617</p>
Sterilizacija	<p>XN/A Produktas parduodamas nesterilizuotas Produktas parduodamas sterilus</p>

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