	DECLARATION OF CONFORMITY
IU COUNCIL D	DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES
	RER: Medtronic Sofamor Danek USA, Inc.
	1800 Pyramid Place
	Memphis, Tennessee 38132
	USA
MEDICAL DEV	ICE: MASTERGRAFT • Granules, MASTERGRAFT • Mini Granules, BICALPHOS(BCP)
	00001
	Reference Product List including GMDN and UMDNS codes
CLASSIFICATION IN ACCORDANCE WITH ANNEX	X IX: Class III, Rule 8
	Reference Product List for specific device classifications
CONFORMITY ASSESSMENT ROL	JTE: Annex II (4)
	Reference Product List for specific device routes
INTO NATIONAL LAW, OF THE PROVISIONS OF CO	
INTO NATIONAL LAW, OF THE PROVISIONS OF CO ALL SUPPORTING DOCUMENTATION IS RETAINED STANDARDS APPLIED: REFER TO LIST OF HARMO	DUNCIL DIRECTIVE 93/42/EEC AND IF APPLICABLE, COMMISSION REGULATION NO. 722/2012. D AT THE PREMISES OF THE MANUFACTURER. NISED – EN STANDARDS FOR WHICH DOCUMENTED EVIDENCE OF COMPLIANCE CAN BE PROVIDED.
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INTO NATIONAL LAW, OF THE PROVISIONS OF CO ALL SUPPORTING DOCUMENTATION IS RETAINED STANDARDS APPLIED: REFER TO LIST OF HARMO THIS LIST IS LOCATED WITH THE TECHNICAL FILE. NOTIFIED BODY: IDENTIFICATION NUMBER: (EC) CERTIFICATE(S): EC REP	DUNCIL DIRECTIVE 93/42/EEC AND IF APPLICABLE, COMMISSION REGULATION NO. 722/2012. D AT THE PREMISES OF THE MANUFACTURER. INISED – EN STANDARDS FOR WHICH DOCUMENTED EVIDENCE OF COMPLIANCE CAN BE PROVIDED. TÜV SÜD PRODUCT SERVICE GMBH RIDLERSTR 65, D-80339 MUNICH, GERMANY 0123 G7 15 03 39040 057 Medtronic B.V.
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Page 1 of 2

RRF040 (QSD009162), Ver. E, Effective: June 13, 2016

D	ECLARATION OF CO			
TO COUNCIL DIRECT	TIVE 93/42/EEC COI		CAL DEVICES	
MANUFACTU	RER: Medtri	onic Sofamor Danek US	iA, Inc.	
		yramid Place		
		his, Tennessee 38132		
	USA			
MEDICAL DEV	IICE: Cenuic	al Stabilization Bundle		
		col File TF001		
			ing GMDN and UMDNS	odes
CLASSIFICATION IN ACCORDANCE WITH ANNE			le 6 and Rule 9; Class IIb,	
	Refere	nce Product List for sp	ecific device classificatio	ns
CONFORMITY ASSESSMENT RO	UTE: Annex	II (-Section 4) and Ann	ex V	
	Refere	ence Product List for sp	ecific device routes	
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DECL	ARATION OF CONFORMITY
TO COUNCIL DIRECTIVE	93/42/EEC CONCERNING MEDICAL DEVICES
MANUFACTURER:	: Medtronic Sofamor Danek USA, Inc.
	1800 Pyramid Place
	Memphis, Tennessee 38132
	USA
MEDICAL DEVICE	: Cervical Fusion bundle
	Technical File TF008
	Reference Product List including GMDN and UMDNS codes
LASSIFICATION IN ACCORDANCE WITH ANNEX IX	: Class Im, Rule 6; Class IIa, Rule 6; Class IIb, Rule 8
	Reference Product List for specific device classifications
CONFORMITY ASSESSMENT ROUTE	: Аплех II (excluding Section 4), Annex V
	Reference Product List for specific device routes
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EGULATION NO. 722/2012. LL SUPPORTING DOCUMENTATION IS RETAINED TANDARDS APPLIED: REFER TO LIST OF HARMON	AT THE PREMISES OF THE MANUFACTURER. IISED EN STANDARDS FOR WHICH DOCUMENTED EVIDENCE OF COMPLIANCE
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ALEGULATION NO. 722/2012. ALL SUPPORTING DOCUMENTATION IS RETAINED STANDARDS APPLIED: REFER TO LIST OF HARMON CAN BE PROVIDED. THIS LIST IS LOCATED WITH TH NOTIFIED BODY: IDENTIFICATION NUMBER: (EC) CERTIFICATE(S): EC REP EUROPEAN REPRESENTATIVE:	AT THE PREMISES OF THE MANUFACTURER. IISED – EN STANDARDS FOR WHICH DOCUMENTED EVIDENCE OF COMPLIANCE HE TECHNICAL FILE. TÜV SÜD PRODUCT SERVICE GMBH RIDLERSTR 65, D-80339 MUNICH, GERMANY 0123 for Class Im, Class Is, and above CER000054, CER000004 Medtronic B.V. Earl Bakkenstraat 10 6422 PJ Heerlen The Netherlands
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DE	CLARATION OF CONFORMITY
TO COUNCIL DIRECT	IVE 93/42/EEC CONCERNING MEDICAL DEVICES
MANUFACTUR	RER: Medtronic Sofamor Danek USA, Inc.
	1800 Pyramid Place
	Memphis, Tennessee 38132
	USA
MEDICAL DEV	VICE: TL Fusion Bundle
	Technical File or Design Dossier Number (TF010)
	Reference Product List including GMDN and UMDNS codes
CLASSIFICATION IN ACCORDANCE WITH ANNE	X IX: Class Im, Class IIa, Rule 6; Class IIb, Rule 8
	Reference Product List for specific device classifications
CONFORMITY ASSESSMENT RO	DUTE: Annex II (-Section 4), Annex V
	Reference Product List for specific device routes
L SUPPORTING DOCUMENTATION IS RETAINE	PROVISIONS OF COUNCIL DIRECTIVE 93/42/EEC AND IF APPLICABLE, COMMISSION ED AT THE PREMISES OF THE MANUFACTURER.
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RRF040 (QSD009162), Ver. E, Effective: June 13, 2015

DECL	ARATION OF CONFORMITY
TO COUNCIL DIRECTIVI	E 93/42/EEC CONCERNING MEDICAL DEVICES
	R: Medtronic Sofamor Danek USA, Inc.
	1800 Pyramid Place
	Memphis, Tennessee 38132
	USA
MEDICAL DEVICE	E: Vertebral and Extremity Fracture Devices
	Technical File Number (TF012)
	Reference Product List including GMDN and UMDN5 codes
CLASSIFICATION IN ACCORDANCE WITH ANNEX I	X: Class 1 (sterile), Rule 1; Class IIa, Rule 6; Class IIa, Rule 9, Class IIb, Rule 8
	Reference Product List for specific device classifications
CONFORMITY ASSESSMENT ROUTI	E: Annex II excluding Section 4, Annex V, Annex VII
	Reference Product List for specific device routes
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