DECLARATION 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:	*MASTERGRAFT® Granules, MASTERGRAFT® Mini Granules, BICALPHOS(BCP)* *DD001* Reference Product List including GMDN and UMDNS codes
CLASSIFICATION IN ACCORDANCE WITH ANNEX IX:	*Class III, Rule 8* Reference Product List for specific device classifications
CONFORMITY ASSESSMENT ROUTE:	*Annex II (4)* Reference Product List for specific device routes

WE, THE MANUFACTURER, UNDER OUR SOLE RESPONSIBILITY, HEREWITH DECLARE THAT THE STATED MEDICAL DEVICES MEET THE TRANSPOSITION INTO NATIONAL LAW, OF THE PROVISIONS OF COUNCIL DIRECTIVE 93/42/EEC AND IF APPLICABLE, COMMISSION REGULATION NO. 722/2012.

ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER.

STANDARDS APPLIED: REFER TO LIST OF HARMONISED – EN STANDARDS FOR WHICH DOCUMENTED EVIDENCE OF COMPLIANCE CAN BE PROVIDED. THIS LIST IS LOCATED WITH THE TECHNICAL FILE.

NOTIFIED BODY:	TÜV SÜD PRODUCT SERVICE GMBH RIDLERSTR 65, D-80339 MUNICH, GERMANY
IDENTIFICATION NUMBER:	*0123*
(EC) CERTIFICATE(S):	*G7 15 03 39040 057*
EC REP EUROPEAN REPRESENTATIVE:	Medtronic B.V. Earl Bakkenstraat 10 6422 PJ Heerlen The Netherlands
START OF CE-MARKING:	DATE OF FIRST CE MARKING (Reference attached list)
SIGNATURE:	Michelle Obenauer 06 Jun 2017
	Michelle Obenauer — DATE
	Regulatory Affairs Director
PLACE:	Memphis, TN, USA

Digitally signed by Cucerenco Olesea
Date: 2019.04.17 10:29:07 EEST
Reason: MoldSign Signature
Location: Moldova

DECLARATION 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 Stabilization Bundle* *Technical File TF001* Reference Product List including GMDN and UMDNS codes
CLASSIFICATION IN ACCORDANCE WITH ANNEX IX:	*Class Im, Rule 6; Class IIa, Rule 6 and Rule 9; Class IIb, Rule 8* Reference Product List for specific device classifications
CONFORMITY ASSESSMENT ROUTE:	*Annex II (-Section 4) and Annex V* Reference Product List for specific device routes

WE, THE MANUFACTURER, UNDER OUR SOLE RESPONSIBILITY, HEREWITH DECLARE THAT THE STATED MEDICAL DEVICES MEET THE TRANSPOSITION INTO NATIONAL LAW, OF THE PROVISIONS OF COUNCIL DIRECTIVE 93/42/EEC AND IF APPLICABLE, COMMISSION REGULATION NO. 722/2012.

ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER.

STANDARDS APPLIED: REFER TO LIST OF HARMONISED – EN STANDARDS FOR WHICH DOCUMENTED EVIDENCE OF COMPLIANCE CAN BE PROVIDED. THIS LIST IS LOCATED WITH THE TECHNICAL FILE.

NOTIFIED BODY:	TÜV SÜD PRODUCT SERVICE GMBH RIDLERSTR 65, D-80339 MUNICH, GERMANY		
IDENTIFICATION NUMBER:	*0123 for Class Im, Class Is, and above*		
(EC) CERTIFICATE(S):	G1151139040059 G2M130639040047	Expiration Date:	4/19/2020 6/30/2018
EC REP EUROPEAN REPRESENTATIVE:	Medtronic B.V. Earl Bakkenstraat 10 6422 PJ Heerlen The Netherlands		
START OF CE-MARKING:	DATE OF FIRST CE MARKING (Reference attached list)		
SIGNATURE:			24 Jan 2018
	NAME Kathryn A. Simpson, PhD REGULATORY AFFAIRS Director or Designee		DATE
	Director, Reg Affairs TITLE		
PLACE:	Memphis, TN, USA		

DECLARATION 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
CLASSIFICATION 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:	*Annex II (excluding Section 4), Annex V* Reference Product List for specific device routes

WE, THE MANUFACTURER, UNDER OUR SOLE RESPONSIBILITY, HEREWITH DECLARE THAT THE STATED MEDICAL DEVICES MEET THE TRANSPOSITION INTO NATIONAL LAW, OF THE PROVISIONS OF COUNCIL DIRECTIVE 93/42/EEC AND IF APPLICABLE, COMMISSION REGULATION NO. 722/2012.

ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER.

STANDARDS APPLIED: REFER TO LIST OF HARMONISED – EN STANDARDS FOR WHICH DOCUMENTED EVIDENCE OF COMPLIANCE CAN BE PROVIDED. THIS LIST IS LOCATED WITH THE TECHNICAL FILE.

NOTIFIED BODY:	TÜV SÜD PRODUCT SERVICE GMBH RIDLERSTR 65, D-80339 MUNICH, GERMANY
IDENTIFICATION NUMBER:	*0123 for Class Im, Class Is, and above*
(EC) CERTIFICATE(S):	*CER000054, CER000004*
EC REP EUROPEAN REPRESENTATIVE:	Medtronic B.V. Earl Bakkenstraat 10 6422 PJ Heerlen The Netherlands
START OF CE-MARKING:	DATE OF FIRST CE MARKING (Reference attached list)
SIGNATURE:	08 Mar 2018
NAME Kathryn H Simpson, PhD REGULATORY AFFAIRS Director or Designee	DATE
Director, Reg Affairs TITLE	
PLACE:	Memphis TN, USA

DECLARATION 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:	*TL Fusion Bundle* *Technical File or Design Dossier Number (TF010)* Reference Product List including GMDN and UMDNS codes
CLASSIFICATION IN ACCORDANCE WITH ANNEX IX:	*Class Im, Class IIa, Rule 6; Class IIb, Rule 8* Reference Product List for specific device classifications
CONFORMITY ASSESSMENT ROUTE:	*Annex II (-Section 4), Annex V* Reference Product List for specific device routes

WE, THE MANUFACTURER, UNDER OUR SOLE RESPONSIBILITY, HEREWITH DECLARE THAT THE STATED MEDICAL DEVICES MEET THE TRANSPOSITION INTO NATIONAL LAW, OF THE PROVISIONS OF COUNCIL DIRECTIVE 93/42/EEC AND IF APPLICABLE, COMMISSION REGULATION NO. 722/2012.

ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER.

STANDARDS APPLIED: REFER TO LIST OF HARMONISED – EN STANDARDS FOR WHICH DOCUMENTED EVIDENCE OF COMPLIANCE CAN BE PROVIDED. THIS LIST IS LOCATED WITH THE TECHNICAL FILE.

NOTIFIED BODY:	TÜV SÜD PRODUCT SERVICE GMBH RIDLERSTR 65, D-80339 MUNICH, GERMANY
IDENTIFICATION NUMBER:	*0123 for Class Im, Class Is, and above*
(EC) CERTIFICATE(S):	*CER000054, CER000004*
EC REP EUROPEAN REPRESENTATIVE:	Medtronic B.V. Earl Bakkenstraat 10 6422 PJ Heerlen The Netherlands
START OF CE-MARKING:	DATE OF FIRST CE MARKING (Reference attached list)
SIGNATURE:	Claire Evans 22DEC2016 Claire Evans DATE
	REGULATORY AFFAIRS Manager TITLE
PLACE:	Memphis, TN USA

DECLARATION 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:	*Vertebral and Extremity Fracture Devices* *Technical File Number (TF012)* Reference Product List including GMDN and UMDNS codes
CLASSIFICATION IN ACCORDANCE WITH ANNEX IX:	*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 ROUTE:	*Annex II excluding Section 4, Annex V, Annex VII* Reference Product List for specific device routes

WE, THE MANUFACTURER, UNDER OUR SOLE RESPONSIBILITY, HEREWITH DECLARE THAT THE STATED MEDICAL DEVICES MEET THE TRANSPOSITION INTO NATIONAL LAW, OF THE PROVISIONS OF COUNCIL DIRECTIVE 93/42/EEC AND IF APPLICABLE, COMMISSION REGULATION NO. 722/2012.

ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER.

STANDARDS APPLIED: REFER TO LIST OF HARMONISED – EN STANDARDS FOR WHICH DOCUMENTED EVIDENCE OF COMPLIANCE CAN BE PROVIDED. THIS LIST IS LOCATED WITH THE TECHNICAL FILE.

NOTIFIED BODY:	TÜV SÜD PRODUCT SERVICE GMBH RIDLERSTR 65, D-80339 MUNICH, GERMANY
IDENTIFICATION NUMBER:	*0123 for Class Im, Class Is, and above*
(EC) CERTIFICATE(S):	*CER000054, CER000049*
EC REP EUROPEAN REPRESENTATIVE:	Medtronic B.V. Earl Bakkenstraat 10 6422 PJ Heerlen The Netherlands
START OF CE-MARKING:	DATE OF FIRST CE MARKING (Reference attached list)
SIGNATURE:	Jeff Sprague 27 OCT 2017 JEFFREY SPRAGUE DATE SR. REGULATORY AFFAIRS PROGRAM MANAGER
PLACE:	Memphis, TN