

EU MDR Declaration of Conformity (DoC)

Manufacturer:	Covidien llc 15 Hampshire St. Mansfield, MA 02048
Manufacturer SRN:	To be determined
Authorized Representative:	Medtronic B.V. Earl Bakkenstraat 10 6422 PJ Heerlen The Netherlands
Authorized Representative SRN:	NL-AR-000006050
Notified Body:	TÜV SÜD Product Service GmbH 0123 Ridlerstraße 65 80339 München / Munich Germany
Conformity Assessment Certificate(s):	G70 077608 0095 Rev. 00 (expires 7-Mar-2027) G12 077608 0097 Rev. 00 (expires 18-July-2027)
Conformity Assessment Route:	Annex IX, Chapter I and III in conjunction with Annex IX Chapter II
Risk Class:	Class III
Classification rule:	Rule 8, Indent 3
Intended purpose:	The intended purpose of the Biosyn™ suture is soft tissue approximation and/or ligation.

Statement:

We, Covidien llc, hereby declare under our sole responsibility that the product(s) specified herein conform to EU Medical Device Regulation 2017/745 and relevant Union Legislation that provides for the issuing of an EU Declaration of Conformity. This is also a declaration made in accordance with the requirements of Clause 1.8 of schedule 3 of the Australian Therapeutic Goods (Medical Devices) Regulations 2002 relating to the stated device.

Union Legislation	Declaration of Conformity Document Number
Not Applicable	Not Applicable

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Medtronic

Place: North Haven, CT
Name: Wing Ng
Title: Regulatory Affairs Director

Signature: 

Date: July 26, 2022

Products Covered

Product Name	Product Identifier	Basic UDI-DI
	CFN	
Biosyn™ 0; Violet 18" GS-21	CM10M	0763000B00001937L
Biosyn™ 1 Violet 18" GS-21	CM11M	0763000B00001937L
Biosyn™ 5-0; Violet 30" CV-11 CV-11	CM126	0763000B00001937L
Biosyn™ 0; Undyed 18" GS-21	CM14M	0763000B00001937L
Biosyn™ 3-0; Violet 30" CV-23 CV-23	CM208	0763000B00001937L
Biosyn™ 1 Violet 36" GS-13	CM222	0763000B00001937L
Biosyn™ 0; Violet 18" GS-25	CM30M	0763000B00001937L
Biosyn™ 1 Violet 18" GS-25	CM31M	0763000B00001937L
Biosyn™ 4-0; Undyed 18" PC-13	CM400	0763000B00001937L
Biosyn™ 5-0; Undyed 18" PC-13	CM401	0763000B00001937L
Biosyn™ 0 VL 30 HGS-21	CM436	0763000B00001937L
Biosyn™ 1 Violet 30" HOS-11	CM528	0763000B00001937L
Biosyn™ 2-0; Undyed 30" GS-11	CM543	0763000B00001937L
Biosyn™ 0; Undyed 30" GS-11	CM544	0763000B00001937L
Biosyn™ 2-0; Violet 30" GU-46 V-20	CM558	0763000B00001937L
Biosyn™ 3-0; Violet 5 x 18" GS-21 DT	CM738M	0763000B00001937L
Biosyn™ 1 VL 60 KV-40 Loop	CM740L	0763000B00001937L
Biosyn™ 0; Violet 60 GS-24 Loop	CM765L	0763000B00001937L
Biosyn™ 1 Violet 60 GS-24 Loop	CM767L	0763000B00001937L
Biosyn™ 1 Violet 60 GS-25 Loop	CM776L	0763000B00001937L
Biosyn™ 0; Violet 60 GS-26 Loop	CM779L	0763000B00001937L
Biosyn™ 1 Violet 96 GS-26 Loop	CM780L	0763000B00001937L
Biosyn™ 0; Violet 60 GS-25 Loop	CM790L	0763000B00001937L
Biosyn™ 2-0; Violet 30" GS-24	CM801	0763000B00001937L
Biosyn™ 3-0; Violet 30" GS-21	CM810	0763000B00001937L
Biosyn™ 2-0; Violet 30" GS-21	CM811	0763000B00001937L
Biosyn™ 0; Violet 30" GS-21	CM812	0763000B00001937L
Biosyn™ 1 Violet 30" GS-21	CM813	0763000B00001937L
Biosyn™ 2-0; Violet 30" GS-11	CM816	0763000B00001937L
Biosyn™ 0; Violet 30" GS-11	CM817	0763000B00001937L
Biosyn™ 2-0; UD 30 KV-34	CM827	0763000B00001937L
Biosyn™ 2-0; Undyed 30" GS-22	CM830	0763000B00001937L
Biosyn™ 0; Undyed 30" GS-22	CM831	0763000B00001937L
Biosyn™ 1 Violet 30" GS-22	CM832	0763000B00001937L
Biosyn™ 3-0; Undyed 30" GS-21	CM842	0763000B00001937L
Biosyn™ 2-0; Undyed 30" GS-21	CM843	0763000B00001937L
Biosyn™ 0; Undyed 30" GS-21	CM844	0763000B00001937L

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Biosyn™ 1 Undyed 30" GS-21	CM845	0763000B00001937L
Biosyn™ 2-0; Violet 30" GS-10	CM879	0763000B00001937L
Biosyn™ 3-0; Violet 30" GS-22	CM882	0763000B00001937L
Biosyn™ 2-0; Violet 30" GS-22	CM883	0763000B00001937L
Biosyn™ 0; Violet 30" GS-22	CM884	0763000B00001937L
Biosyn™ 2-0; Violet 36" GS-25	CM903	0763000B00001937L
Biosyn™ 0; Violet 36" GS-25	CM904	0763000B00001937L
Biosyn™ 1 Violet 36" GS-25	CM905	0763000B00001937L
Biosyn™ 0; Violet 36" GS-24	CM914	0763000B00001937L
Biosyn™ 3-0; Violet 36" GS-21	CM922	0763000B00001937L
Biosyn™ 2-0; Violet 36" GS-21	CM923	0763000B00001937L
Biosyn™ 0; Violet 36" GS-21	CM924	0763000B00001937L
Biosyn™ 1 Violet 36" GS-21	CM925	0763000B00001937L
Biosyn™ 1 Violet 18" BGS-25	CM949M	0763000B00001937L
Biosyn™ 1 Violet 36" BGS-24	CM951	0763000B00001937L
Biosyn™ 2-0; Undyed 36" GS-21	CM953	0763000B00001937L
Biosyn™ 0; Undyed 36" GS-21	CM954	0763000B00001937L
Biosyn™ 3-0; Undyed 36" GS-24	CM962	0763000B00001937L
Biosyn™ 0; Undyed 36" GS-24	CM964	0763000B00001937L
Biosyn™ 1 Violet 36" GS-24	CM966	0763000B00001937L
Biosyn™ 0; Undyed 36" GS-25	CM974	0763000B00001937L
Biosyn™ 1 Undyed 36" GS-25	CM975	0763000B00001937L
Biosyn™ 3-0; Undyed 54" GS-11 GS-21	CM991	0763000B00001937L
Biosyn™ 2-0; Violet 5 x 18" GS-21 DT	CM9M	0763000B00001937L
Biosyn™ 0; Violet 5 x 18" BTP-1 DT	CMT740M	0763000B00001937L
Biosyn™ 1 Violet 5 x 18" BTP-1 DT	CMT741M	0763000B00001937L
Biosyn™ 0; Violet 60 BTP-X Loop	CMT789L	0763000B00001937L
Biosyn™ 2-0; Violet 30" BTP-1	CMT811	0763000B00001937L
Biosyn™ 0; Violet 30" BTP-1	CMT812	0763000B00001937L
Biosyn™ 1 Violet 5 x 18" BTP-X DT	CMT949M	0763000B00001937L
Biosyn™ 0; Violet 5 x 18" BTP-X DT	CMT950M	0763000B00001937L
Biosyn™ 0; Undyed 36" BTP-1	CMT967	0763000B00001937L
Biosyn™ 0; Undyed 36" BTP-X	CMT974	0763000B00001937L
Biosyn™ 4-0; Violet 30" V-20	GM121	0763000B00001937L
Biosyn™ 3-0; Violet 30" V-20	GM122	0763000B00001937L
Biosyn™ 2-0; Violet 30" V-20	GM123	0763000B00001937L
Biosyn™ 2-0; Violet 36" V-20	GM125	0763000B00001937L
Biosyn™ 4-0; Violet 30" CV-25	GM181	0763000B00001937L
Biosyn™ 4-0 Violet 30" CV-25	GM181M	0763000B00001937L
Biosyn™ 2-0; Violet 30" CV-25	GM183	0763000B00001937L
Biosyn™ 3-0; Violet 30" V-30	GM222	0763000B00001937L
Biosyn™ 2-0; Violet 30" V-30	GM223	0763000B00001937L
Biosyn™ 3-0; Undyed 30" V-26	GM226	0763000B00001937L

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Biosyn™ 2-0; Undyed 30" V-26	GM227	0763000B00001937L
Biosyn™ 4-0; Violet 30" CV-25 CV-25	GM281	0763000B00001937L
Biosyn™ 3-0; Violet 36" CV-25 CV-25	GM282	0763000B00001937L
Biosyn™ 4-0; Violet 36" CV-25 CV-25	GM291	0763000B00001937L
Biosyn™ 4-0; Undyed 30" V-20	GM321	0763000B00001937L
Biosyn™ 3-0; Undyed 30" V-20	GM322	0763000B00001937L
Biosyn™ 2-0; Undyed 30" V-20	GM323	0763000B00001937L
Biosyn™ 3-0; Violet 30" CV-25	GM324	0763000B00001937L
Biosyn™ 2-0; Violet 36" V-30	GM326	0763000B00001937L
Biosyn™ 0; Violet 36" V-30	GM327	0763000B00001937L
Biosyn™ 3-0; Violet 36" V-20 V-20	GM332	0763000B00001937L
Biosyn™ 4-0; Violet 18" CV-25	GM34M	0763000B00001937L
Biosyn™ 4-0; Violet 30" V-20 V-20	GM421	0763000B00001937L
Biosyn™ 4-0; Violet 36" V-20 V-20	GM432	0763000B00001937L
Biosyn™ 3-0 Violet 30" V-20	GM67M	0763000B00001937L
Biosyn™ 3-0; Undyed 18" V-20	GM69M	0763000B00001937L
Biosyn™ 5-0; Violet 30" CV-22	GM875	0763000B00001937L
Biosyn™ 3-0; Violet 18" CV-25	GMJ33M	0763000B00001937L
BIOSYN* 4-0 Violet 18" CV-25	GMJ34M	0763000B00001937L
Biosyn™ 5-0; Violet 18" CV-23	GMJ45M	0763000B00001937L
Biosyn™ 4-0 Violet 5 cm x 45 cm CV-23	GMJ46M	0763000B00001937L
Biosyn™ 5-0; Violet 18" CV-22	GMJ54M	0763000B00001937L
Biosyn™ 2-0; Violet 18" V-20	GMJ62M	0763000B00001937L
Biosyn™ 3-0; Violet 18" V-20	GMJ63M	0763000B00001937L
Biosyn™ 4-0; Violet 18" V-20	GMJ64M	0763000B00001937L
Biosyn™ 3-0; Undyed 30" BTV-20	GMT226	0763000B00001937L
Biosyn™ 0; Violet 60" Standard Length	M114	0763000B00001937L
Biosyn™ 2-0; Undyed 18"	M23	0763000B00001937L
Biosyn™ 4-0; Violet 18"	M31	0763000B00001937L
Biosyn™ 3-0; Violet 18"	M32	0763000B00001937L
Biosyn™ 2-0; Violet 18"	M33	0763000B00001937L
Biosyn™ 3-0 Violet 18"	M72	0763000B00001937L
Biosyn™ 0; Violet 3 x 18"	M74	0763000B00001937L
Biosyn™ 1 Violet 18"	M75	0763000B00001937L
Biosyn™ 5-0; Undyed 18" PR-1	SM1614	0763000B00001937L
Biosyn™ 6-0; Undyed 18" P-10	SM3625	0763000B00001937L
Biosyn™ 5-0; Undyed 18" P-10	SM3626	0763000B00001937L
Biosyn™ 4-0; Undyed 18" CVF-21	SM431	0763000B00001937L
Biosyn™ 5-0; Undyed 18" CVF-21	SM432	0763000B00001937L
Biosyn™ 4-0; Undyed 30 CVF-21	SM434	0763000B00001937L
Biosyn™ Undyed 5-0 18 P-12	SM5624	0763000B00001937L
Biosyn™ Undyed 4-0 18 P-12	SM5627	0763000B00001937L
Biosyn™ Undyed 3-0 18 P-12	SM5628	0763000B00001937L

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Biosyn™ Undyed 4-0 30 P-12	SM5637	0763000B00001937L
Biosyn™ 4-0; Undyed 30 P-12	SM5637GMDL	0763000B00001937L
Biosyn™ Undyed 3-0 30 P-12	SM5638	0763000B00001937L
Biosyn™ Undyed 4-0 30 P-14	SM5678	0763000B00001937L
Biosyn™ Undyed 4-0 18 P-14	SM5679	0763000B00001937L
Biosyn™ Undyed 3-0 30 P-14	SM5679G	0763000B00001937L
Biosyn™ Undyed 5-0 18 P-13	SM5687	0763000B00001937L
Biosyn™ 5-0; Undyed 18 P-13	SM5687GMDL	0763000B00001937L
Biosyn™ Undyed 6-0 18 P-13	SM5688	0763000B00001937L
Biosyn™ UD 4-0 18 P-13	SM5690	0763000B00001937L
Biosyn™ 3-0; Violet 30" C-23	SM632	0763000B00001937L
Biosyn™ 4-0; Violet 30" C-23	SM633	0763000B00001937L
Biosyn™ 3-0; Undyed 30" SC-2	SM643	0763000B00001937L
Biosyn™ 4-0; Undyed 30" SC-2	SM644	0763000B00001937L
Biosyn™ 5-0; Undyed 30" C-13	SM690	0763000B00001937L
Biosyn™ 4-0; Undyed 30" C-13	SM691	0763000B00001937L
Biosyn™ 4-0 Undyed 30" C-13	SM691G	0763000B00001937L
Biosyn™ 3-0; Undyed 30" C-14	SM693	0763000B00001937L
Biosyn™ 4-0; Violet 30" C-13	SM791	0763000B00001937L
Biosyn™ 3-0; Undyed 30" C-13	SM822	0763000B00001937L
Biosyn™ 2-0; Undyed 30" C-14	SM823	0763000B00001937L
Biosyn™ 3-0; Violet 18" C-23	SM83M	0763000B00001937L
Biosyn™ 3-0; Violet 30" C-13	SM922	0763000B00001937L
Biosyn™ 2-0; Violet 30" C-14	SM923	0763000B00001937L
Biosyn™ 6-0; Violet 30" CV-23	UM201	0763000B00001937L
Biosyn™ 5-0; Violet 30" CV-23	UM202	0763000B00001937L
Biosyn™ 4-0; Violet 30" CV-23	UM203	0763000B00001937L
Biosyn™ 3-0; Violet 30" CV-23	UM204	0763000B00001937L
Biosyn™ 5-0; Undyed 30" CV-23	UM213	0763000B00001937L
Biosyn™ 4-0; Undyed 30" CV-23	UM214	0763000B00001937L
Biosyn™ 3-0; Undyed 30" CV-23	UM215	0763000B00001937L
Biosyn™ 3-0; Violet 30" GU-45 GU-45	UM243	0763000B00001937L
Biosyn™ 2-0; Violet 30" GU-45	UM245	0763000B00001937L
Biosyn™ 2-0; Undyed 30" GU-45	UM345	0763000B00001937L
Biosyn™ O Violet 30 GU-44	UM383	0763000B00001937L
Biosyn™ 4-0; Violet 30" CV-23 CV-23	UM403	0763000B00001937L
Biosyn™ 0; Violet 30" GU-46	UM877	0763000B00001937L
Biosyn™ 2-0; Violet 30" GU-46	UM878	0763000B00001937L
Biosyn™ 3-0; Violet 30" GU-46	UM879	0763000B00001937L
Biosyn™ 6-0; Undyed 30" CV-22	UM886	0763000B00001937L
Biosyn™ 0; Undyed 30" GU-46	UM977	0763000B00001937L
Biosyn™ 2-0; Undyed 30" GU-46	UM978	0763000B00001937L
Biosyn™ 6-0; Violet 30" CV-22	UM986	0763000B00001937L

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Biosyn™ 5-0; Undyed 18" DX-19	XM822	0763000B00001937L
Biosyn™ 4-0; Undyed 18" DX-19	XM823	0763000B00001937L
Biosyn™ 5-0; Undyed 18" DX-13	XM834	0763000B00001937L
Biosyn™ 4-0; Undyed 18" DX-16	XM845	0763000B00001937L
Biosyn™ 5/0 30" VIOLET SNG CV-15	XX2215	0763000B00001937L
Biosyn™ 3-0; Violet 30"	XX5009	0763000B00001937L
Biosyn™ Size 3-0 USP (2 Metric); 36 inches 90 c	XX5028	0763000B00001937L
Biosyn™ 3-0; Violet 30" GU-46 D/A	XX5086	0763000B00001937L
Biosyn™ 1 96" Violet C-25	XX5138	0763000B00001937L
Biosyn™ 3-0; 30" Violet BTV-20	XX5229J	0763000B00001937L

Common Specification(s)

The following common specifications were used to demonstrate conformity: Not applicable

Number	Date of Issue	Title
Not applicable	Not applicable	Not applicable