ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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www.zlg.de
BS-MDR-099

Product Service

EU Technical Documentation Assessment Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapter II
(Implantable Class IIb Devices and Class III Devices)

No. G70 077608 0095 Rev. 00

Manufacturer:

Covidien llc
15 Hampshire Street
Mansfield, MA 02048
USA

SRN Manufacturer: Not available at issuance date of this certificate.

Authorized Representative:

Medtronic B.V.
Earl Bakkenstraat 10, 6422 PJ Heerlen, THE NETHERLANDS

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has drawn up and presented a Technical Documentation according to Annex II and III of the Regulation (EU) 2017/745 on medical devices. Details on devices covered by the Technical Documentation are described on the following page(s). The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The technical documentation assessment included an assessment of the clinical evaluation assessment. The conformity assessment has been carried out according to Annex IX chapter II of this regulation with a positive result.
Changes to the approved device, where such changes could affect the safety and performance of the device or the conditions prescribed for use of the device, shall require approval from the notified body TÜV SÜD Product Service GmbH. In order to place the devices on the market with CE-marking, an EU Quality Management System Certificate pursuant to Annex IX chapters I and III is necessary in addition to this EU Technical Documentation Assessment Certificate. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G70 077608 0095 Rev. 00

Report No.: 713194269

Valid from: 2022-03-08
Valid until: 2027-03-07

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2022-03-08

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Classification: III

Device Group: H010101 - ABSORBABLE SYNTHETIC SUTURES

Basic UDI-DI: 0763000B00001937L

Intended Purpose: The intended purpose of the Biosyn™ suture is soft tissue approximation and/or ligation.

Device(s): Biosyn™ Monofilament Synthetic Absorbable Suture

The validity of this certificate depends on conditions and/or is limited to the following: ./.

Article/Model Names	Article/Model Numbers
Biosyn™ 0; Violet 18" GS-21	CM10M
Biosyn™ 1 Violet 18" GS-21	CM11M
Biosyn™ 5-0; Violet 30" CV-11 CV-11	CM126
Biosyn™ 0; Undyed 18" GS-21	CM14M
Biosyn™ 3-0; Violet 30" CV-23 CV-23	CM208
Biosyn™ 1 Violet 36" GS-13	CM222
Biosyn™ 0; Violet 18" GS-25	CM30M
Biosyn™ 1 Violet 18" GS-25	CM31M
Biosyn™ 4-0; Undyed 18" PC-13	CM400

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Biosyn™ 5-0; Undyed 18" PC-13	CM401
Biosyn™ O VL 30 HGS-21	CM436
Biosyn™ 1 Violet 30" HOS-11	CM528
Biosyn™ 2-0; Undyed 30" GS-11	CM543
Biosyn™ 0; Undyed 30" GS-11	CM544
Biosyn™ 2-0; Violet 30" GU-46 V-20	CM558
Biosyn™ 3-0; Violet 5 x 18" GS-21 DT	CM738M
Biosyn™ 1 VL 60 KV-40 Loop	CM740L
Biosyn™ 0; Violet 60 GS-24 Loop	CM765L
Biosyn™ 1 Violet 60 GS-24 Loop	CM767L
Biosyn™ 1 Violet 60 GS-25 Loop	CM776L
Biosyn™ 0; Violet 60 GS-26 Loop	CM779L
Biosyn™ 1 Violet 96 GS-26 Loop	CM780L
Biosyn™ 0; Violet 60 GS-25 Loop	CM790L
Biosyn™ 2-0; Violet 30" GS-24	CM801
Biosyn™ 3-0; Violet 30" GS-21	CM810
Biosyn™ 2-0; Violet 30" GS-21	CM811

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Biosyn™ 0; Violet 30" GS-21	CM812
Biosyn™ 1 Violet 30" GS-21	CM813
Biosyn™ 2-0; Violet 30" GS-11	CM816
Biosyn™ 0; Violet 30" GS-11	CM817
Biosyn™ 2-0; UD 30 KV-34	CM827
Biosyn™ 2-0; Undyed 30" GS-22	CM830
Biosyn™ 0; Undyed 30" GS-22	CM831
Biosyn™ 1 Violet 30" GS-22	CM832
Biosyn™ 3-0; Undyed 30" GS-21	CM842
Biosyn™ 2-0: Undyed 30" GS-21	CM843
Biosyn™ 0; Undyed 30" GS-21	CM844
Biosyn™ 1 Undyed 30" GS-21	CM845
Biosyn™ 2-0; Violet 30" GS-10	CM879
Biosyn™ 3-0; Violet 30" GS-22	CM882
Biosyn™ 2-0; Violet 30" GS-22	CM883
Biosyn™ 0; Violet 30" GS-22	CM884
Biosyn™ 2-0; Violet 36" GS-25	CM903
Biosyn™ 0; Violet 36" GS-25	CM904

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Biosyn™ 1 Violet 36" GS-25	CM905
Biosyn™ 0; Violet 36" GS-24	CM914
Biosyn™ 3-0; Violet 36" GS-21	CM922
Biosyn™ 2-0; Violet 36" GS-21	CM923
Biosyn™ 0; Violet 36" GS-21	CM924
Biosyn™ 1 Violet 36" GS-21	CM925
Biosyn™ 1 Violet 18" BGS-25	CM949M
Biosyn™ 1 Violet 36" BGS-24	CM951
Biosyn™ 2-0; Undyed 36" GS-21	CM953
Biosyn™ 0; Undyed 36" GS-21	CM954
Biosyn™ 3-0; Undyed 36" GS-24	CM962
Biosyn™ 0; Undyed 36" GS-24	CM964
Biosyn™ 1 Violet 36" GS-24	CM966
Biosyn™ 0; Undyed 36" GS-25	CM974
Biosyn™ 1 Undyed 36" GS-25	CM975
Biosyn™ 3-0; Undyed 54" GS-11 GS-21	CM991
Biosyn™ 2-0; Violet 5 x 18" GS-21 DT	CM9M
Biosyn™ 0; Violet 5 x 18" BTP-1 DT	CMT740M

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Biosyn™ 1 Violet 5 x 18" BTP-1 DT	CMT741M
Biosyn™ 0,;Violet 60 BTP-X Loop	CMT789L
Biosyn™ 2-0; Violet 30" BTP-1	CMT811
Biosyn™ 0; Violet 30" BTP-1	CMT812
Biosyn™ 1 Violet 5 x 18" BTP-X DT	CMT949M
Biosyn™ 0; Violet 5 x 18" BTP-X DT	CMT950M
Biosyn™ 0; Undyed 36" BTP-1	CMT967
Biosyn™ 0; Undyed 36" BTP-X	CMT974
Biosyn™ 4-0; Violet 30" V-20	GM121
Biosyn™ 3-0; Violet 30" V-20	GM122
Biosyn™ 2-0; Violet 30" V-20	GM123
Biosyn™ 2-0; Violet 36" V-20	GM125
Biosyn™ 4-0; Violet 30" CV-25	GM181
Biosyn™ 4-0 Violet 30" CV-25	GM181M
Biosyn™ 2-0; Violet 30" CV-25	GM183
Biosyn™ 3-0; Violet 30" V-30	GM222
Biosyn™ 2-0; Violet 30" V-30	GM223
Biosyn™ 3-0; Undyed 30" V-26	GM226

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Biosyn™ 2-0; Undyed 30" V-26	GM227
Biosyn™ 4-0; Violet 30" CV-25 CV-25	GM281
Biosyn™ 3-0; Violet 36" CV-25 CV-25	GM282
Biosyn™ 4-0; Violet 36" CV-25 CV-25	GM291
Biosyn™ 4-0; Undyed 30" V-20	GM321
Biosyn™ 3-0; Undyed 30" V-20	GM322
Biosyn™ 2-0; Undyed 30" V-20	GM323
Biosyn™ 3-0; Violet 30" CV-25	GM324
Biosyn™ 2-0; Violet 36" V-30	GM326
Biosyn™ 0; Violet 36" V-30	GM327
Biosyn™ 3-0; Violet 36" V-20 V-20	GM332
Biosyn™ 4-0; Violet 18" CV-25	GM34M
Biosyn™ 4-0; Violet 30" V-20 V-20	GM421
Biosyn™ 4-0; Violet 36" V-20 V-20	GM432
Biosyn™ 3-0 Violet 30" V-20	GM67M
Biosyn™ 3-0; Undyed 18" V-20	GM69M
Biosyn™ 5-0; Violet 30" CV-22	GM875
Biosyn™ 3-0; Violet 18" CV-25	GMJ33M
BIOSYN* 4-0 Violet 18" CV-25	GMJ34M

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Biosyn™ 5-0; Violet 18" CV-23	GMJ45M
Biosyn™ 4-0 Violet 5 cm x 45 cm CV-23	GMJ46M
Biosyn™ 5-0; Violet 18" CV-22	GMJ54M
Biosyn™ 2-0; Violet 18" V-20	GMJ62M
Biosyn™ 3-0; Violet 18" V-20	GMJ63M
Biosyn™ 4-0; Violet 18" V-20	GMJ64M
Biosyn™ 3-0; Undyed 30" BTV-20	GMT226
Biosyn™ 0; Violet 60" Standard Length	M114
Biosyn™ 2-0; Undyed 18"	M23
Biosyn™ 4-0; Violet 18"	M31
Biosyn™ 3-0; Violet 18"	M32
Biosyn™ 2-0; Violet 18"	M33
Biosyn™ 3-0 Violet 18"	M72
Biosyn™ 0; Violet 3x18"	M74
Biosyn™ 1 Violet 18"	M75
Biosyn™ 5-0; Undyed 18" PR-1	SM1614
Biosyn™ 6-0; Undyed 18" P-10	SM3625
Biosyn™ 5-0; Undyed 18" P-10	SM3626
Biosyn™ 4-0; Undyed 18" CVF-21	SM431

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Biosyn™ 5-0; Undyed 18" CVF-21	SM432
Biosyn™ 4-0; Undyed 30 CVF-21	SM434
Biosyn™ Undyed 5-0 18 P-12	SM5624
Biosyn™ Undyed 4-0 18 P-12	SM5627
Biosyn™ Undyed 3-0 18 P-12	SM5628
Biosyn™ Undyed 4-0 30 P-12	SM5637
Biosyn™ 4-0; Undyed 30 P-12	SM5637GMDL
Biosyn™ Undyed 3-0 30 P-12	SM5638
Biosyn™ Undyed 4-0 30 P-14	SM5678
Biosyn™ Undyed 4-0 18 P-14	SM5679
Biosyn™ Undyed 3-0 30 P-14	SM5679G
Biosyn™ Undyed 5-0 18 P-13	SM5687
Biosyn™ 5-0; Undyed 18 P-13	SM5687GMDL
Biosyn™ Undyed 6-0 18 P-13	SM5688
Biosyn™ UD 4-0 18 P-13	SM5690
Biosyn™ 3-0; Violet 30" C-23	SM632
Biosyn™ 4-0; Violet 30" C-23	SM633

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Biosyn™ 3-0; Undyed 30" SC-2	SM643
Biosyn™ 4-0; Undyed 30" SC-2	SM644
Biosyn™ 5-0; Undyed 30" C-13	SM690
Biosyn™ 4-0; Undyed 30" C-13	SM691
Biosyn™ 4-0 Undyed 30" C-13	SM691G
Biosyn™ 3-0; Undyed 30" C-14	SM693
Biosyn™ 4-0; Violet 30" C-13	SM791
Biosyn™ 3-0; Undyed 30" C-13	SM822
Biosyn™ 2-0; Undyed 30" C-14	SM823
Biosyn™ 3-0; Violet 18" C-23	SM83M
Biosyn™ 3-0; Violet 30" C-13	SM922
Biosyn™ 2-0; Violet 30" C-14	SM923
Biosyn™ 6-0; Violet 30" CV-23	UM201
Biosyn™ 5-0; Violet 30" CV-23	UM202
Biosyn™ 4-0; Violet 30" CV-23	UM203
Biosyn™ 3-0; Violet 30" CV-23	UM204
Biosyn™ 5-0; Undyed 30" CV-23	UM213
Biosyn™ 4-0; Undyed 30" CV-23	UM214
Biosyn™ 3-0; Undyed 30" CV-23	UM215

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Biosyn™ 3-0; Violet 30" GU-45 GU-45	UM243
Biosyn™ 2-0; Violet 30" GU-45	UM245
Biosyn™ 2-0; Undyed 30" GU-45	UM345
Biosyn™ O Violet 30 GU-44	UM383
Biosyn™ 4-0; Violet 30" CV-23 CV-23	UM403
Biosyn™ 0; Violet 30" GU-46	UM877
Biosyn™ 2-0; Violet 30" GU-46	UM878
Biosyn™ 3-0; Violet 30" GU-46	UM879
Biosyn™ 6-0; Undyed 30" CV-22	UM886
Biosyn™ 0; Undyed 30" GU-46	UM977
Biosyn™ 2-0; Undyed 30" GU-46	UM978
Biosyn™ 6-0; Violet 30" CV-22	UM986
Biosyn™ 5-0; Undyed 18" DX-19	XM822
Biosyn™ 4-0; Undyed 18" DX-19	XM823
Biosyn™ 5-0; Undyed 18" DX-13	XM834
Biosyn™ 4-0; Undyed 18" DX-16	XM845
Biosyn™ 5/0 30" VIOLET SNG CV-15	XX2215
Biosyn™ 3-0; Violet 30"	XX5009
Biosyn™ Size 3-0 USP (2 Metric); 36 inches 90 c	XX5028

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Biosyn™ 3-0; Violet 30" GU-46 D/A	XX5086
Biosyn™ 1 96" Violet C-25	XX5138
Biosyn™ 3-0; 30" Violet BTV-20	XX5229J

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