



C E R T I F I C A T E

EC Design-Examination Certificate

93/42/EEC Directive of Medical Devices Annex II, Section 4

With the expire of the certificate M.2016.106.7195 the validity of the certificate M.2016.106.7195-1 will also end.

Company Name : Yurim Medical Co., Ltd.

Company Address : (303-ho,310-ho,312-ho), 125, Osongsaengmyeong 2-ro,
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Chungcheongbuk-do, KOREA

Related Directives and Annex : 93/42/EEC Medical Devices Directive - Annex II
(Section 4)

Product : 1- Sterile Polydioxanone Suture with Needle - Class III
2- Sterile PLLA(Poly-L-Lactic Acid) Suture with Needle - Class III

GMDN : 16584, 63575

Product Types are attached.

Certificate Number : M.2016.106.7195-1

Report Number : MD.1013.K.IB-1

Initial Assessment Date : 15.05.2016

Registration Date : 13.12.2016

Revision Date / No : 17.01.2019/04

Expiry Date : 12.12.2021


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CE
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The EC desing examination certificate refers to the above mentioned product. UDEM hereby declares that the requirements of Annex II, section 4 of the 93/42/EEC Directive have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance audits, defined by Annex II, section 5 of the aforementioned directive. This certificate remains as the property of UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co. to whom it must be returned upon request. The above named company and UDEM must keep a copy of this certificate for 5 years from the registration of the certificate. Usage of the CE mark is under the responsibility of the manufacturer with the completion of EC Declaration of Conformity. The above mentioned company must notify all changes related with the approved product to UDEM. If UDEM will not renew the expiry date of this certificate in question, the mentioned company should stop placing the product on the market. The validity of the certificate can be checked through www.udem.com.tr.

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This document containing 4 (four) pages is the Annex of the Certificate with the revision number 04, with the number M.2016.106.7195-1 and with the registration date of 13.12.2016 with the revision date of 17.01.2019 issued for "Yurim Medical Co., Ltd." by UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş. that is giving service as Notified Body with the ID No: 2292 according to 93/42/EEC Medical Devices

Synthetic, Monofilament suture, Non-coated, Violet sterile polydioxanone suture with needle		
GMDN NO: 16584		
USP: 7-0, 6-0, 5-0, 4-0, 3-0, 2-0, 0, 1, 2		
EP: 0.5, 0.7, 1, 1.5, 2, 3, 3.5, 4, 5		
Suture Lengths : 15mm TO 420mm		
Needle Lengths : 13mm TO 152mm		
Needle Shapes : Straight		
Needle Properties: Sharp keen Needle type, Cannula type		
Color: Suture (D&C VIOLET #2)		
Coated information: Non-coated		
Sterile Polydioxanone Suture with Needle Model List		
Traditional general needle		
General PDO suture with general needle (289 models)		Cog PDO suture with general needle (305 models)
<ul style="list-style-type: none">• Normal (46 models): YRN series(including YRN19-01)• Pair Spiral (12 models): YRT series(including YRT25-01)• Normal Spiral (43 models): YRS series(including YRS19-01)• 2 Fix Pair Spiral (10 models): YR2T series(including YR2T25-01)• Duo Normal Spiral (14 models): YRDS series(including YRDS25-01)• 4 Wind Normal (43 models): YR2XN series(including YR2XN19-01)• Pair-Normal Spiral (10 models): YRTS series(including YRTS25-01)• Normal Coil (43 models): YRNC series(including YRNC19-01)• Multi Fill (8 models): YRMF series(including YRMF21-01)• Cavern Fill (60 models): YRCF series(including YRCF21-01)	<ul style="list-style-type: none">• AB type (21 models)• AP type (21 models)• BC type (21 models)• BP type (21 models)• BSP type (5 models)• CA type (21 models)• DA type (2 models)• DB type (21 models)• DSP type (10 models)• FA type (21 models)• FB type (21 models)• FC type (21 models)• FD type (21 models)• FE type (21 models)• FG type (21 models)• SC type (6 models)• FE BP type (21 models)• ST type (1 model)• SZ type (6 models)• SE type (2 models)	YRPN series (including YRPN19-07)
Grip general needle		
General PDO suture with grip needle (115 models)		Cog PDO suture with grip needle (62 models)
<ul style="list-style-type: none">• Normal (18 models): YRN-G series(including YRN25-01-G)• Pair Spiral (8 models): YRT-G series(including YRT25-01-G)• Normal Spiral (14 models): YRS-G series(including YRS25-03-G)• Duo Normal Spiral (7 models): YRDS-G series(including YRDS25-01-G)• Multi Fill (8 models): YRMF-G series(including YRMF21-01-G)• Cavern Fill (60 models): YRCF-G series(including YRCF21-01-G)	<ul style="list-style-type: none">• BSP type (3 models)• CA type (7 models)• FB type (3 models)• FC type (2 models)• FE type (9 models)• FG type (2 models)• SC type (6 models)• FE BP type (21 models)• ST type (1 model)• SZ type (6 models)	YRPN-G series (including YRPN27-06-G)



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Blunt needle		• SE type (2 models)	
General "W" blunt needle		Grip "W" blunt needle	
General PDO suture with general "W" blunt needle (4 models)		Cog PDO suture with grip "W" blunt needle (55 models)	
<ul style="list-style-type: none">• Normal (2 models): YRN-W series(including YRN30-01-W)• Normal Spiral (2 models): YRS-W series(including YRS30-01-W)		<ul style="list-style-type: none">• CA type (7 models)• FA type (1 model)• FE type (9models)• FG type (2 models)• SC type (6 models)• FE BP type (21 models)• ST type (1 model)• SZ type (6 models)• SE type (2 models)	
Cog PDO suture with general "W" blunt needle (267 models)		YRPN-WG series (including YRPN19-46-WG)	
<ul style="list-style-type: none">• AB type (21 models)• AP type (21 models)• BC type (21 models)• BP type (21 models)• CA type (21 models)• DB type (21 models)• FA type (21 models)• FC type (21 models)• FD type (21 models)• FE type (21 models)• FG type (21 models)• SC type (6 models)• FE BP type (21 models)• ST type (1 model)• SZ type (6 models)• SE type (2 models)	YRPN-W series (including YRPN19-07-W)		
General "L" blunt needle		Grip "L" blunt needle	
General PDO suture with general "L" blunt needle (68 models)		General PDO suture with grip "L" blunt needle (68 models)	
<ul style="list-style-type: none">• Multi Fill (8 models): YRMF-L series(including YRMF21-01-L)• Cavern Fill (60 models): YRCF-L series(including YRCF21-01-L)		<ul style="list-style-type: none">• Multi Fill (8 models): YRMF-LG series(including YRMF21-01-LG)• Cavern Fill (60 models): YRCF-LG series(including YRCF21-01-LG)	
Cog PDO suture with general "L" blunt needle (290 models)		Cog PDO suture with grip "L" blunt needle (55 models)	
<ul style="list-style-type: none">• AB type (21 models)• AP type (21 models)• BC type (21 models)• BP type (21 models)• CA type (21 models)• DA type (2 models)• DB type (21 models)• FA type (21 models)• FB type (21 models)• FC type (21 models)• FD type (21 models)• FE type (21 models)• FG type (21 models)• SC type (6 models)• FE BP type (21 models)	YRPN-L series (including YRPN19-07-L)	<ul style="list-style-type: none">• CA type (7 models)• FA type (1 model)• FE type (9 models)• FG type (2 models)• SC type (6 models)• FE BP type (21 models)• ST type (1 model)• SZ type (6 models)• SE type (2 models)	YRPN-LG series (including YRPN19-46-LG)



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<ul style="list-style-type: none">• ST type (1 model)• SZ type (6 models)• SE type (2 models)			
General "C" blunt needle		Grip "C" blunt needle	
Cog PDO suture with general "C" blunt needle (290 models)		Cog PDO suture with grip "C" blunt needle (39 models)	
<ul style="list-style-type: none">• AB type (21 models)• AP type (21 models)• BC type (21 models)• BP type (21 models)• CA type (21 models)• DA type (2 models)• DB type (21 models)• FA type (21 models)• FB type (21 models)• FC type (21 models)• FD type (21 models)• FE type (21 models)• FG type (21 models)• SC type (6 models)• FE BP type (21 models)• ST type (1 model)• SZ type (6 models)• SE type (2 models)	YRPN-C series (including YRPN19-07-C)	<ul style="list-style-type: none">• FA type (1 model)• FE type (9 models)• FG type (2 models)• SC type (6 models)• FE BP type (21 models)	YRPN-CG series (including YRPN21-58-CG)
Straight needle			
Cog PDO suture with Straight needle (56 models)			
<ul style="list-style-type: none">• FC type (16 models): YRDN-FC series(including YRDN-FC-CI-01)• FE type (16 models): YRDN-FE series(including YRDN-FE-CI-01)• SC type (8 models): YRDN-SC series(including YRDN-SC-CI-01)• ST type (8 models): YRDN-ST series(including YRDN-ST-CI-01)• SZ type (8 models): YRDN-SZ series(including YRDN-SZ-CI-01)			

Synthetic, Monofilament suture, Non-coated, Colorless, Sterile PLLA(Poly-L-Lactic Acid) Suture with Needle	
GMDN NO: 63575	
USP: 6-0, 5-0, 4-0, 3-0, 2-0	
EP: 0.7, 1, 1.5, 2, 3	
Suture Lengths : 15mm TO 180mm	
Needle Lengths : 13mm TO 100mm	
Needle Shapes : Straight	
Needle Properties: Sharp keen Needle type, Cannula type	
Color: Suture (Colorless)	
Coated information: Non-coated	
Sterile PLLA(Poly-L-Lactic Acid) Suture with Needle Model List	
Traditional general needle	
General PLLA suture with general needle (140 models)	Cog PLLA suture with general needle (161 models)



<ul style="list-style-type: none"> • Normal (39 models): YRN-PL series(including YRN-PL21-01) • Pair Spiral (12 models): YRT-PL series(including YRT-PL25-01) • Normal Spiral (37 models): YRS-PL series(including YRS-PL21-01) • Duo Normal Spiral (14 models): YRDS-PL series(including YRDS-PL25-01) • Normal Coil (38 models): YRNC-PL series(including YRNC-PL19-01) 	<ul style="list-style-type: none"> • AB type (16 models) • AP type (16 models) • BC type (10 models) • BP type (16 models) • CA type (16 models) • DB type (16 models) • FA type (5 models) • FB type (16 models) • FC type (16 models) • FD type (16 models) • FE type (16 models) • FG type (2 models) 	YRPN-PL series (including YRPN-PL19-07)
Grip general needle		
General PLLA suture with grip needle (47 models)	Cog PLLA suture with grip needle (31 models)	
<ul style="list-style-type: none"> • Normal (18 models): YRN-PL-G series(including YRN-PL25-01-G) • Pair Spiral (8 models): YRT-PL-G series(including YRT-PL25-01-G) • Normal Spiral (14 models): YRS-PL-G series(including YRS-PL25-03-G) • Duo Normal Spiral (7 models): YRDS-PL-G series(including YRDS-PL25-01-G) 	<ul style="list-style-type: none"> • CA type (16 models) • FB type (3 models) • FC type (3 models) • FE type (9 models) 	YRPN-PL-G series (including YRPN-PL19-43-G)
Blunt needle		
General “W” blunt needle		Grip “W” blunt needle
General PLLA suture with general “W” blunt needle (4 models)		Cog PLLA suture with grip “W” blunt needle (26 models)
<ul style="list-style-type: none"> • Normal (2 models): YRN-PL-W series(including YRN-PL30-01-W) • Normal Spiral (2 models): YRS-PL-W series(including YRS-PL30-01-W) 	<ul style="list-style-type: none"> • CA type (16 models) • FA type (1 model) • FE type (9 models) 	YRPN-PL-WG series (including YRPN-PL19-43-WG)
Cog PLLA suture with general “W” blunt needle (26 models)		
<ul style="list-style-type: none"> • CA type (16 models) • FA type (1 model) • FE type (9 models) 	YRPN-PL-W series (including YRPN-PL19-43-W)	
General “L” blunt needle		Grip “L” blunt needle
Cog PLLA suture with general “L” blunt needle (26 models)		Cog PLLA suture with grip “L” blunt needle (26 models)
<ul style="list-style-type: none"> • CA type (16 models) • FA type (1 model) • FE type (9 models) 	YRPN-PL-L series (including YRPN-PL19-43-L)	<ul style="list-style-type: none"> • CA type (16 models) • FA type (1 model) • FE type (9 models)
		YRPN-PL-LG series (including YRPN-PL19-43-LG)
General “C” blunt needle		Grip “C” blunt needle
Cog PLLA suture with general “C” blunt needle (26 models)		Cog PLLA suture with grip “C” blunt needle (26 models)
<ul style="list-style-type: none"> • CA type (16 models) • FA type (1 model) • FE type (9 models) 	YRPN-PL-C series (including YRPN-PL19-43-C)	<ul style="list-style-type: none"> • CA type (16 models) • FA type (1 model) • FE type (9 models)
		YRPN-PL-CG series (including YRPN-PL19-43-CG)



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