



EC CERTIFICATE

Full Quality Assurance System Medical Devices Directive 93/42/EEC Annex II (Excluding Section 4)

M.2017.106.8756-1 Design Examination Certificate Was Prepared for Class III Products Defined in This Certificate.

Company Name : İnvamed Sağlık İlaç San. ve Tic. A.Ş

Company Address : Maliköy Anadolu OSB 30 Ağustos Cad. No:13 Sincan ANKARA / TURKEY

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

Product : Sterile Drug-released PTA Baloon - Class III

GMDN : 62551

This certificate has been designed due to Ministry of Health's 80977004-511.14-137598 numbered scientific opinion on 25.10.2016, scope 93/42/AT Annex I Article 7.4

Product Types are attached.

Certificate Number : M.2017.106.8756

Report Number : MD.3091.YB

Initial Assessment Date : 14.03.2016

Registration Date : 09.08.2017

Recertification Assessment Date : 03.01.2020

Reissue Date : 22.12.2020/01

Revision Date /No : -

Expiry Date : 27.05.2024



UDEM International Certification
Auditing Training Centre Industry
and Trade Inc. Co.

UDEM hereby declares that the requirements of Annex II, excluding 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 forementioned directive. According to Annex II, section 4 an EC design- examination certificate is required for placing the Class III devices on the market. UDEM's responsibility for class I devices covered by the EC certificate is limited to manufacturing issues related to safeguarding and maintaining sterile conditions, if the device is sterile; and manufacturing issues related to product's conformity with metrological requirements, if it has measurement function. 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



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This document containing 8 (eight) pages is the Annex of the Certificate with the number M.2017.106.8756 and with the registration date of 09.08.2017 and with the re-issue date 22.12.2020 issued for "İnvamed Sağlık İlaç ve Tic. A.Ş." 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 Directive.

OTW Drug-Released Balloons with 0.014 "Guide Wire (Catheter Shaft: 120 cm)							
Reference No	Balloon diameter (mm)	Balloon length (mm)	Catheter Shaft length (cm)	Reference No	Balloon diameter (mm)	Balloon length (mm)	Catheter Shaft length (cm)
BTK2020S	2,0	20	120	BTK20100S	2.0	100	120
BTK2520S	2,5	20	120	BTK25100S	2.5	100	120
BTK3020S	3,0	20	120	BTK30100S	3.0	100	120
BTK3520S	3,5	20	120	BTK35100S	3.5	100	120
BTK4020S	4.0	20	120	BTK40100S	4.0	100	120
BTK4520S	4.5	20	120	BTK45100S	4.5	100	120
BTK5020S	5.0	20	120	BTK50100S	5.0	100	120
BTK2040S	2,0	40	120	BTK20120S	2.0	120	120
BTK2540S	2,5	40	120	BTK25120S	2.5	120	120
BTK3040S	3,0	40	120	BTK30120S	3.0	120	120
BTK3540S	3,5	40	120	BTK35120S	3.5	120	120
BTK4040S	4.0	40	120	BTK40120S	4.0	120	120
BTK4540S	4.5	40	120	BTK50120S	4.5	120	120
BTK5040S	5.0	40	120	BTK50120S	5.0	120	120
BTK2060S	2,0	60	120	BTK20150S	2.0	150	120
BTK2560S	2,5	60	120	BTK25150S	2.5	150	120
BTK3060S	3,0	60	120	BTK30150S	3.0	150	120
BTK3560S	3,5	60	120	BTK35150S	3.5	150	120
BTK4060S	4.0	60	120	BTK40150S	4.0	150	120
BTK4560S	4.5	60	120	BTK45150S	4.5	150	120
BTK5060S	5.0	60	120	BTK50150S	5.0	150	120
BTK2080S	2.0	80	120	BTK20220S	2.0	220	120
BTK2580S	2.5	80	120	BTK25220S	2.5	220	120
BTK3080S	3.0	80	120	BTK30220S	3.0	220	120
BTK3580S	3.5	80	120	BTK35220S	3.5	220	120
BTK4080S	4.0	80	120	BTK40220S	4.0	220	120
BTK4580S	4.5	80	120	BTK45220S	4.5	220	120
BTK5080S	5.0	80	120	BTK50220S	5.0	220	120

OTW Drug-Released Balloons with 0.014 "Guide Wire (Catheter Shaft: 150 cm)							
Reference No	Balloon diameter (mm)	Balloon length (mm)	Catheter Shaft length (cm)	Reference No	Balloon diameter (mm)	Balloon length (mm)	Catheter Shaft length (cm)
BTK1520L	1,5	20	150	BTK15100L	1.5	100	150
BTK2020L	2,0	20	150	BTK20100L	2.0	100	150
BTK2520L	2,5	20	150	BTK25100L	2.5	100	150
BTK3020L	3,0	20	150	BTK30100L	3.0	100	150
BTK3520L	3,5	20	150	BTK35100L	3.5	100	150
BTK4020L	4.0	20	150	BTK40100L	4.0	100	150





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BTK4520L	4.5	20	150	BTK45100L	4.5	100	150
BTK5020L	5.0	20	150	BTK50100L	5.0	100	150
BTK1540L	1,5	40	150	BTK15120L	1.5	120	150
BTK2040L	2,0	40	150	BTK20120L	2.0	120	150
BTK2540L	2,5	40	150	BTK25120L	2.5	120	150
BTK3040L	3,0	40	150	BTK30120L	3.0	120	150
BTK3540L	3,5	40	150	BTK35120L	3.5	120	150
BTK4040L	4.0	40	150	BTK40120L	4.0	120	150
BTK4540L	4.5	40	150	BTK45120L	4.5	120	150
BTK5040L	5.0	40	150	BTK50120L	5.0	120	150
BTK1560L	1,5	60	150	BTK15150L	1.5	150	150
BTK2060L	2,0	60	150	BTK20150L	2.0	150	150
BTK2560L	2,5	60	150	BTK25150L	2.5	150	150
BTK3060L	3,0	60	150	BTK30150L	3.0	150	150
BTK3560L	3,5	60	150	BTK35150L	3.5	150	150
BTK4060L	4.0	60	150	BTK40150L	4.0	150	150
BTK4560L	4.5	60	150	BTK45150L	4.5	150	150
BTK5060L	5.0	60	150	BTK50150L	5.0	150	150
BTK1580L	1.5	80	150	BTK15220L	1.5	220	150
BTK2080L	2.0	80	150	BTK20220L	2.0	220	150
BTK2580L	2.5	80	150	BTK25220L	2.5	220	150
BTK3080L	3.0	80	150	BTK30220L	3.0	220	150
BTK3580L	3.5	80	150	BTK35220L	3.5	220	150
BTK4080L	4.0	80	150	BTK40220L	4.0	220	150
BTK4580L	4.5	80	150	BTK45220L	4.5	220	150
BTK5080L	5.0	80	150	BTK50220L	5.0	220	150

OTW Drug-Released Balloons with 0.018 "Guidewire (catheter: 90 cm)							
Reference No	Balloon diameter (mm)	Balloon length (mm)	Catheter Shaft length (cm)	Reference No	Balloon diameter (mm)	Balloon length (mm)	Catheter Shaft length (cm)
LPOTW2020S	2.0	20	90	LPOTW20100S	2.0	100	90
LPOTW2520S	2.5	20	90	LPOTW25100S	2.5	100	90
LPOTW3020S	3.0	20	90	LPOTW30100S	3.0	100	90
LPOTW3520S	3.5	20	90	LPOTW35100S	3.5	100	90
LPOTW4020S	4.0	20	90	LPOTW40100S	4.0	100	90
LPOTW4520S	4.5	20	90	LPOTW45100S	4.5	100	90
LPOTW5020S	5.0	20	90	LPOTW50100S	5.0	100	90
LPOTW6020S	6.0	20	90	LPOTW60100S	6.0	100	90
LPOTW7020S	7.0	20	90	LPOTW70100S	7.0	100	90
LPOTW8020S	8.0	20	90	LPOTW80100S	8.0	100	90
LPOTW2040S	2.0	40	90	LPOTW20120S	2.0	120	90
LPOTW2540S	2.5	40	90	LPOTW25120S	2.5	120	90
LPOTW3040S	3.0	40	90	LPOTW30120S	3.0	120	90
LPOTW3540S	3.5	40	90	LPOTW35120S	3.5	120	90





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LPOTW4040S	4.0	40	90	LPOTW40120S	4.0	120	90
LPOTW4540S	4.5	40	90	LPOTW45120S	4.5	120	90
LPOTW5040S	5.0	40	90	LPOTW50120S	5.0	120	90
LPOTW6040S	6.0	40	90	LPOTW60120S	6.0	120	90
LPOTW7040S	7.0	40	90	LPOTW70120S	7.0	120	90
LPOTW8040S	8.0	40	90	LPOTW80120S	8.0	120	90
LPOTW2060S	2.0	60	90	LPOTW20150S	2.0	150	90
LPOTW2560S	2.5	60	90	LPOTW25150S	2.5	150	90
LPOTW3060S	3.0	60	90	LPOTW30150S	3.0	150	90
LPOTW3560S	3.5	60	90	LPOTW35150S	3.5	150	90
LPOTW4060S	4.0	60	90	LPOTW40150S	4.0	150	90
LPOTW4560S	4.5	60	90	LPOTW45150S	4.5	150	90
LPOTW5060S	5.0	60	90	LPOTW50150S	5.0	150	90
LPOTW6060S	6.0	60	90	LPOTW60150S	6.0	150	90
LPOTW7060S	7.0	60	90	LPOTW70150S	7.0	150	90
LPOTW8060S	8.0	60	90	LPOTW80150S	8.0	150	90
LPOTW2080S	2.0	80	90	LPOTW20220S	2.0	220	90
LPOTW2580S	2.5	80	90	LPOTW25220S	2.5	220	90
LPOTW3080S	3.0	80	90	LPOTW30220S	3.0	220	90
LPOTW3580S	3.5	80	90	LPOTW35220S	3.5	220	90
LPOTW4080S	4.0	80	90	LPOTW40220S	4.0	220	90
LPOTW4580S	4.5	80	90	LPOTW45220S	4.5	220	90
LPOTW5080S	5.0	80	90	LPOTW50220S	5.0	220	90
LPOTW6080S	6.0	80	90	LPOTW60220S	6.0	220	90
LPOTW7080S	7.0	80	90	LPOTW70220S	7.0	220	90
LPOTW8080S	8.0	80	90	LPOTW80220S	8.0	220	90

OTW Drug-Released Balloons with 0.018 "Guidewire (Catheter: 120 cm)							
Reference No	Balloon diameter (mm)	Balloon length (mm)	Catheter Shaft length (cm)	Reference No	Balloon diameter (mm)	Balloon length (mm)	Catheter Shaft length (cm)
LPOTW2020M	2.0	20	120	LPOTW20100M	2.0	100	120
LPOTW2520M	2.5	20	120	LPOTW25100M	2.5	100	120
LPOTW3020M	3.0	20	120	LPOTW30100M	3.0	100	120
LPOTW3520M	3.5	20	120	LPOTW35100M	3.5	100	120
LPOTW4020M	4.0	20	120	LPOTW40100M	4.0	100	120
LPOTW4520M	4.5	20	120	LPOTW45100M	4.5	100	120
LPOTW5020M	5.0	20	120	LPOTW50100M	5.0	100	120
LPOTW6020M	6.0	20	120	LPOTW60100M	6.0	100	120
LPOTW7020M	7.0	20	120	LPOTW70100M	7.0	100	120
LPOTW8020M	8.0	20	120	LPOTW80100M	8.0	100	120
LPOTW2040M	2.0	40	120	LPOTW20120M	2.0	120	120
LPOTW2540M	2.5	40	120	LPOTW25120M	2.5	120	120
LPOTW3040M	3.0	40	120	LPOTW30120M	3.0	120	120
LPOTW3540M	3.5	40	120	LPOTW35120M	3.5	120	120
LPOTW4040M	4.0	40	120	LPOTW40120M	4.0	120	120
LPOTW4540M	4.5	40	120	LPOTW45120M	4.5	120	120
LPOTW5040M	5.0	40	120	LPOTW50120M	5.0	120	120



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LPOTW6040M	6.0	40	120	LPOTW60120M	6.0	120	120
LPOTW7040M	7.0	40	120	LPOTW70120M	7.0	120	120
LPOTW8040M	8.0	40	120	LPOTW80120M	8.0	120	120
LPOTW2060M	2.0	60	120	LPOTW20150M	2.0	150	120
LPOTW2560M	2.5	60	120	LPOTW25150M	2.5	150	120
LPOTW3060M	3.0	60	120	LPOTW30150M	3.0	150	120
LPOTW3560M	3.5	60	120	LPOTW35150M	3.5	150	120
LPOTW4060M	4.0	60	120	LPOTW40150M	4.0	150	120
LPOTW4560M	4.5	60	120	LPOTW45150M	4.5	150	120
LPOTW5060M	5.0	60	120	LPOTW50150M	5.0	150	120
LPOTW6060M	6.0	60	120	LPOTW60150M	6.0	150	120
LPOTW7060M	7.0	60	120	LPOTW70150M	7.0	150	120
LPOTW8060M	8.0	60	120	LPOTW80150M	8.0	150	120
LPOTW2080M	2.0	80	120	LPOTW20220M	2.0	220	120
LPOTW2580M	2.5	80	120	LPOTW25220M	2.5	220	120
LPOTW3080M	3.0	80	120	LPOTW30220M	3.0	220	120
LPOTW3580M	3.5	80	120	LPOTW35220M	3.5	220	120
LPOTW4080M	4.0	80	120	LPOTW40220M	4.0	220	120
LPOTW4580M	4.5	80	120	LPOTW45220M	4.5	220	120
LPOTW5080M	5.0	80	120	LPOTW50220M	5.0	220	120
LPOTW6080M	6.0	80	120	LPOTW60220M	6.0	220	120
LPOTW7080M	7.0	80	120	LPOTW70220M	7.0	220	120
LPOTW8080M	8.0	80	120	LPOTW80220M	8.0	220	120

OTW Drug-Released Balloons with 0.018 "Guidewire (catheter length: 135cm)							
Reference No	Balloon diameter (mm)	Balloon length (mm)	Catheter Shaft length (cm)	Reference No	Balloon diameter (mm)	Balloon length (mm)	Catheter Shaft length (cm)
LPOTW2020L	2.0	20	135	LPOTW20100L	2.0	100	135
LPOTW2520L	2.5	20	135	LPOTW25100L	2.5	100	135
LPOTW3020L	3.0	20	135	LPOTW30100L	3.0	100	135
LPOTW3520L	3.5	20	135	LPOTW35100L	3.5	100	135
LPOTW4020L	4.0	20	135	LPOTW40100L	4.0	100	135
LPOTW4520L	4.5	20	135	LPOTW45100L	4.5	100	135
LPOTW5020L	5.0	20	135	LPOTW50100L	5.0	100	135
LPOTW6020L	6.0	20	135	LPOTW60100L	6.0	100	135
LPOTW7020L	7.0	20	135	LPOTW20120L	2.0	120	135
LPOTW8020L	8.0	20	135	LPOTW25120L	2.5	120	135
LPOTW2040L	2.0	40	135	LPOTW30120L	3.0	120	135
LPOTW2540L	2.5	40	135	LPOTW35120L	3.5	120	135
LPOTW3040L	3.0	40	135	LPOTW40120L	4.0	120	135
LPOTW3540L	3.5	40	135	LPOTW45120L	4.5	120	135
LPOTW4040L	4.0	40	135	LPOTW50120L	5.0	120	135
LPOTW4540L	4.5	40	135	LPOTW60120L	6.0	120	135
LPOTW5040L	5.0	40	135	LPOTW20150L	2.0	150	135
LPOTW6040L	6.0	40	135	LPOTW25150L	2.5	150	135
LPOTW7040L	7.0	40	135	LPOTW30150L	3.0	150	135





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LPOTW8040L	8.0	40	135	LPOTW35150L	3.5	150	135
LPOTW2060L	2.0	60	135	LPOTW40150L	4.0	150	135
LPOTW2560L	2.5	60	135	LPOTW45150L	4.5	150	135
LPOTW3060L	3.0	60	135	LPOTW50150L	5.0	150	135
LPOTW3560L	3.5	60	135	LPOTW60150L	6.0	150	135
LPOTW4060L	4.0	60	135	LPOTW20220L	2.0	220	135
LPOTW4560L	4.5	60	135	LPOTW25220L	2.5	220	135
LPOTW5060L	5.0	60	135	LPOTW30220L	3.0	220	135
LPOTW6060L	6.0	60	135	LPOTW35220L	3.5	220	135
LPOTW7060L	7.0	60	135	LPOTW40220L	4.0	220	135
LPOTW8060L	8.0	60	135	LPOTW45220L	4.5	220	135
LPOTW2080L	2.0	80	135	LPOTW50220L	5.0	220	135
LPOTW2580L	2.5	80	135	LPOTW60220L	6.0	220	135
LPOTW3080L	3.0	80	135				
LPOTW3580L	3.5	80	135				
LPOTW4080L	4.0	80	135				
LPOTW4580L	4.5	80	135				
LPOTW5080L	5.0	80	135				
LPOTW6080L	6.0	80	135				

OTW Drug-Released Balloons with 0.035 "Guidewire (Catheter Shaft: 80 cm)							
Reference No	Balloon diameter (mm)	Balloon length (mm)	Catheter Shaft length (cm)	Reference No	Balloon diameter (mm)	Balloon length (mm)	Catheter Shaft length (cm)
TER320S	3,0	20	80 cm	TER3100S	3,0	100	80 cm
TER420S	4.0	20	80 cm	TER41000S	4.0	100	80 cm
TER4520S	4.5	20	80 cm	TER45100S	4.5	100	80 cm
TER520S	5.0	20	80 cm	TER5100S	5.0	100	80 cm
TER5520S	5.5	20	80 cm	TER55100S	5.5	100	80 cm
TER620S	6.0	20	80 cm	TER6100S	6.0	100	80 cm
TER6520S	6.5	20	80 cm	TER65100S	6.5	100	80 cm
TER720S	7.0	20	80 cm	TER7100S	7.0	100	80 cm
TER820S	8.0	20	80 cm	TER8100S	8.0	100	80 cm
TER340S	3,0	40	80 cm	TER3120S	3.0	120	80 cm
TER440S	4.0	40	80 cm	TER4120S	4.0	120	80 cm
TER540S	5.0	40	80 cm	TER45120S	4.5	120	80 cm
TER5540S	5.5	40	80 cm	TER5120S	5.0	120	80 cm
TER640S	6.0	40	80 cm	TER55120S	5.5	120	80 cm
TER6540S	6.5	40	80 cm	TER6120S	6.0	120	80 cm
TER740S	7.0	40	80 cm	TER65120S	6.5	120	80 cm
TER840S	8.0	40	80 cm	TER7120S	7.0	120	80 cm
TER360S	3,0	60	80 cm	TER8120S	8.0	120	80 cm
TER460S	4.0	60	80 cm	TER3150S	3,0	150	80 cm
TER4560S	4.5	60	80 cm	TER4150S	4.0	150	80 cm





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TER560S	5.0	60	80 cm	TER45150S	4.5	150	80 cm
TER5560S	5.5	60	80 cm	TER5150S	5.0	150	80 cm
TER660S	6.0	60	80 cm	TER55150S	5.5	150	80 cm
TER660S	6.5	60	80 cm	TER6150S	6.0	150	80 cm
TER760S	7.0	60	80 cm	TER65150S	6.5	150	80 cm
TER860S	8.0	60	80 cm	TER7150S	7.0	150	80 cm
TER340S	3,0	80	80 cm	TER8150S	8.0	150	80 cm
TER440S	4.0	80	80 cm	TER300S	3.0	200	80 cm
TER4540S	4.5	80	80 cm	TER4200S	4.0	200	80 cm
TER540S	5.0	80	80 cm	TER45200S	4.5	200	80 cm
TER5540S	5.5	80	80 cm	TER5200S	5.0	200	80 cm
TER640S	6.0	80	80 cm	TER55200S	5.5	200	80 cm
TER6540S	6.5	80	80 cm	TER6200S	6.0	200	80 cm
TER740S	7.0	80	80 cm	TER65200S	6.5	200	80 cm
TER840S	8.0	80	80 cm	TER7200S	7.0	200	80 cm
				TER8200S	8.0	200	80 cm

OTW Drug-Released Balloons with 0.035 "Guidewire (Catheter Shaft: 135 cm)							
Reference No	Balloon diameter (mm)	Balloon length (mm)	Catheter Shaft length (cm)	Reference No	Balloon diameter (mm)	Balloon length (mm)	Catheter Shaft length (cm)
TER320L	3,0	20	135	TER3100L	3,0	100	135
TER420L	4.0	20	135	TER4100L	4.0	100	135
TER4520L	4.5	20	135	TER45100L	4.5	100	135
TER520L	5.0	20	135	TER5100L	5.0	100	135
TER5520L	5.5	20	135	TER55100L	5.5	100	135
TER620L	6.0	20	135	TER6100L	6.0	100	135
TER6520L	6.5	20	135	TER65100L	6.5	100	135
TER720L	7.0	20	135	TER7100L	7.0	100	135
TER820L	8.0	20	135	TER8100L	8.0	100	135
TER340L	3,0	40	135	TER9100L	9.0	100	135
TER440L	4.0	40	135	TER10100L	10.0	100	135
TER4540L	4.5	40	135	TER12100L	12.0	100	135
TER540L	5.0	40	135	TER3120L	3.0	120	135
TER5540L	5.5	40	135	TER4120L	4.0	120	135
TER640L	6.0	40	135	TER45120L	4.5	120	135
TER6540L	6.5	40	135	TER5120L	5.0	120	135
TER740L	7.0	40	135	TER55120L	5.5	120	135
TER840L	8.0	40	135	TER6120L	6.0	120	135
TER360L	3,0	60	135	TER65120L	6.5	120	135
TER460L	4.0	60	135	TER7120L	7.0	120	135
TER4560L	4.5	60	135	TER8120L	8.0	120	135
TER560L	5.0	60	135	TER9120L	9.0	120	135
TER5560L	5.5	60	135	TER10120L	10.0	120	135
TER660L	6.0	60	135	TER3150L	3,0	150	135
TER6560L	6.5	60	135	TER4150L	4.0	150	135
TER760L	7.0	60	135	TER45150L	4.5	150	135
TER860L	8.0	60	135	TER5150L	5.0	150	135
TER960L	9.0	60	135	TER55150L	5.5	150	135



This document containing 8 (eight) pages is the Annex of the Certificate with the number M.2017.106.8756 and with the registration date of 09.08.2017 and with the re-issue date 22.12.2020 issued for "İnvamed Sağlık İlaç ve Tic. A.Ş." 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 Directive.

TER1060L	10.0	60	135	TER6150L	6.0	150	135
TER380L	3.0	80	135	TER65150L	6.5	150	135
TER480L	4.0	80	135	TER7150L	7.0	150	135
TER4580L	4.5	80	135	TER8150L	8.0	150	135
TER580L	5.0	80	135	TER9150L	9.0	150	135
TER5580L	5.5	80	135	TER10150L	10.0	150	135
TER680L	6.0	80	135	TER3200L	3.0	200	135
TER6580L	6.5	80	135	TER4200L	4.0	200	135
TER780L	7.0	80	135	TER45200L	4.5	200	135
TER880L	8.0	80	135	TER5200L	5.0	200	135
TER980L	9.0	80	135	TER55200L	5.5	200	135
TER1080L	10.0	80	135	TER6200L	6.0	200	135
TER1280L	12.0	80	135	TER65200L	6.5	200	135
				TER7200L	7.0	200	135
				TER8200L	8.0	200	135

RX Drug-Released Balloons with 0.014 "Guidewire (Catheter Shaft: 120 cm)				RX Drug-Released Balloons with 0.014 "Guidewire (Catheter Shaft: 150 cm)			
Reference No	Balloon diameter (mm)	Balloon length (mm)	Catheter Shaft length (cm)	Reference No	Balloon diameter (mm)	Balloon length (mm)	Catheter Shaft length (cm)
LPRX2010M	2.0	10	120	LPRX2010X	2.0	10	150
LPRX2510M	2.5	10	120	LPRX2510X	2.5	10	150
LPRX27510M	2.75	10	120	LPRX27510X	2.75	10	150
LPRX3010M	3.0	10	120	LPRX3010X	3.0	10	150
LPRX3510M	3.5	10	120	LPRX3510X	3.5	10	150
LPRX4010M	4.0	10	120	LPRX4010X	4.0	10	150
LPRX2015M	2.0	15	120	LPRX2015X	2.0	15	150
LPRX2515M	2.5	15	120	LPRX2515X	2.5	15	150
LPRX27515M	2.75	15	120	LPRX27515X	2.75	15	150
LPRX3015M	3.0	15	120	LPRX3015X	3.0	15	150
LPRX3515M	3.5	15	120	LPRX3515X	3.5	15	150
LPRX4015M	4.0	15	120	LPRX4015X	4.0	15	150
LPRX2017M	2.0	17	120	LPRX2017X	2.0	17	150
LPRX2517M	2.5	17	120	LPRX2517X	2.5	17	150
LPRX27517M	2.75	17	120	LPRX27517X	2.75	17	150
LPRX3017M	3.0	17	120	LPRX3017X	3.0	17	150
LPRX3517M	3.5	17	120	LPRX3517X	3.5	17	150
LPRX4017M	4.0	17	120	LPRX4017X	4.0	17	150
LPRX2020M	2.0	20	120	LPRX2020X	2.0	20	150
LPRX2520M	2.5	20	120	LPRX2520X	2.5	20	150
LPRX27520M	2.75	20	120	LPRX27520X	2.75	20	150
LPRX3020M	3.0	20	120	LPRX3020X	3.0	20	150
LPRX3520M	3.5	20	120	LPRX3520X	3.5	20	150
LPRX4020M	4.0	20	120	LPRX4020X	4.0	20	150



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LPRX2026M	2,0	26	120	LPRX2026X	2,0	26	150
LPRX2526M	2,5	26	120	LPRX2526X	2,5	26	150
LPRX27526M	2.75	26	120	LPRX27526X	2.75	26	150
LPRX3026M	3.0	26	120	LPRX3026X	3.0	26	150
LPRX3526M	3.5	26	120	LPRX3526X	3.5	26	150
LPRX4026M	4.0	26	120	LPRX4026X	4.0	26	150
LPRX2030M	2,0	30	120	LPRX2030X	2,0	30	150
LPRX2530M	2,5	30	120	LPRX2530X	2,5	30	150
LPRX27530M	2.75	30	120	LPRX27530X	2.75	30	150
LPRX3030M	3.0	30	120	LPRX3030X	3.0	30	150
LPRX3530M	3.5	30	120	LPRX3530X	3.5	30	150
LPRX4030M	4.0	30	120	LPRX4030X	4.0	30	150



EC DESIGN EXAMINATION CERTIFICATE

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

With the expire of the certificate M.2017.106.8756 the validity of the certificate
M.2017.106.8756-1 will also end.

Company Name : Invamed Sağlık İlaç San. ve Tic. A.Ş

Company Address : Malıköy Anadolu OSB 30 Ağustos Cad. No:13 Sincan
ANKARA / TURKEY

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

Product : Sterile Drug-released PTA Baloon - Class III

GMDN : 62551

This certificate has been designed due to Ministry of Health's 80977004-511.14-137598 numbered
scientific opinion on 25.10.2016, scope 93/42/AT Annex I Article 7.4

Product Types are attached.

Certificate Number : M.2017.106.8756-1
Report Number : MD.3091.YB
Initial Assessment Date : 14.03.2016
Registration Date : 09.08.2017
Recertification Assessment Date : 03.01.2020
Reissue Date : 22.12.2020/01
Revision Date /No : -
Expiry Date : 27.05.2024



UDEM International Certification
Auditing Training Centre Industry
and Trade Inc. Co.



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.

Address: Mutlukent Mahallesi 2073 Sokak (Eski 93 Sokak) No:10 Çankaya – Ankara – TURKEY

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OTW Drug-Released Balloons with 0.014 "Guide Wire (Catheter Shaft: 120 cm)							
Reference No	Balloon diameter (mm)	Balloon length (mm)	Catheter Shaft length (cm)	Reference No	Balloon diameter (mm)	Balloon length (mm)	Catheter Shaft length (cm)
BTK2020S	2,0	20	120	BTK20100S	2.0	100	120
BTK2520S	2,5	20	120	BTK25100S	2.5	100	120
BTK3020S	3,0	20	120	BTK30100S	3.0	100	120
BTK3520S	3,5	20	120	BTK35100S	3.5	100	120
BTK4020S	4.0	20	120	BTK40100S	4.0	100	120
BTK4520S	4.5	20	120	BTK45100S	4.5	100	120
BTK5020S	5.0	20	120	BTK50100S	5.0	100	120
BTK2040S	2,0	40	120	BTK20120S	2.0	120	120
BTK2540S	2,5	40	120	BTK25120S	2.5	120	120
BTK3040S	3,0	40	120	BTK30120S	3.0	120	120
BTK3540S	3,5	40	120	BTK35120S	3.5	120	120
BTK4040S	4.0	40	120	BTK40120S	4.0	120	120
BTK4540S	4.5	40	120	BTK50120S	4.5	120	120
BTK5040S	5.0	40	120	BTK50120S	5.0	120	120
BTK2060S	2,0	60	120	BTK20150S	2.0	150	120
BTK2560S	2,5	60	120	BTK25150S	2.5	150	120
BTK3060S	3,0	60	120	BTK30150S	3.0	150	120
BTK3560S	3,5	60	120	BTK35150S	3.5	150	120
BTK4060S	4.0	60	120	BTK40150S	4.0	150	120
BTK4560S	4.5	60	120	BTK45150S	4.5	150	120
BTK5060S	5.0	60	120	BTK50150S	5.0	150	120
BTK2080S	2.0	80	120	BTK20220S	2.0	220	120
BTK2580S	2.5	80	120	BTK25220S	2.5	220	120
BTK3080S	3.0	80	120	BTK30220S	3.0	220	120
BTK3580S	3.5	80	120	BTK35220S	3.5	220	120
BTK4080S	4.0	80	120	BTK40220S	4.0	220	120
BTK4580S	4.5	80	120	BTK45220S	4.5	220	120
BTK5080S	5.0	80	120	BTK50220S	5.0	220	120

OTW Drug-Released Balloons with 0.014 "Guide Wire (Catheter Shaft: 150 cm)							
Reference No	Balloon diameter (mm)	Balloon length (mm)	Catheter Shaft length (cm)	Reference No	Balloon diameter (mm)	Balloon length (mm)	Catheter Shaft length (cm)
BTK1520L	1,5	20	150	BTK15100L	1.5	100	150
BTK2020L	2,0	20	150	BTK20100L	2.0	100	150
BTK2520L	2,5	20	150	BTK25100L	2.5	100	150
BTK3020L	3,0	20	150	BTK30100L	3.0	100	150
BTK3520L	3,5	20	150	BTK35100L	3.5	100	150
BTK4020L	4.0	20	150	BTK40100L	4.0	100	150





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BTK4520L	4.5	20	150	BTK45100L	4.5	100	150
BTK5020L	5.0	20	150	BTK50100L	5.0	100	150
BTK1540L	1,5	40	150	BTK15120L	1.5	120	150
BTK2040L	2,0	40	150	BTK20120L	2.0	120	150
BTK2540L	2,5	40	150	BTK25120L	2.5	120	150
BTK3040L	3,0	40	150	BTK30120L	3.0	120	150
BTK3540L	3,5	40	150	BTK35120L	3.5	120	150
BTK4040L	4.0	40	150	BTK40120L	4.0	120	150
BTK4540L	4.5	40	150	BTK45120L	4.5	120	150
BTK5040L	5.0	40	150	BTK50120L	5.0	120	150
BTK1560L	1,5	60	150	BTK15150L	1.5	150	150
BTK2060L	2,0	60	150	BTK20150L	2.0	150	150
BTK2560L	2,5	60	150	BTK25150L	2.5	150	150
BTK3060L	3,0	60	150	BTK30150L	3.0	150	150
BTK3560L	3,5	60	150	BTK35150L	3.5	150	150
BTK4060L	4.0	60	150	BTK40150L	4.0	150	150
BTK4560L	4.5	60	150	BTK45150L	4.5	150	150
BTK5060L	5.0	60	150	BTK50150L	5.0	150	150
BTK1580L	1.5	80	150	BTK15220L	1.5	220	150
BTK2080L	2.0	80	150	BTK20220L	2.0	220	150
BTK2580L	2.5	80	150	BTK25220L	2.5	220	150
BTK3080L	3.0	80	150	BTK30220L	3.0	220	150
BTK3580L	3.5	80	150	BTK35220L	3.5	220	150
BTK4080L	4.0	80	150	BTK40220L	4.0	220	150
BTK4580L	4.5	80	150	BTK45220L	4.5	220	150
BTK5080L	5.0	80	150	BTK50220L	5.0	220	150

OTW Drug-Released Balloons with 0.018 "Guidewire (catheter: 90 cm)							
Reference No	Balloon diameter (mm)	Balloon length (mm)	Catheter Shaft length (cm)	Reference No	Balloon diameter (mm)	Balloon length (mm)	Catheter Shaft length (cm)
LPOTW2020S	2.0	20	90	LPOTW20100S	2.0	100	90
LPOTW2520S	2.5	20	90	LPOTW25100S	2.5	100	90
LPOTW3020S	3.0	20	90	LPOTW30100S	3.0	100	90
LPOTW3520S	3.5	20	90	LPOTW35100S	3.5	100	90
LPOTW4020S	4.0	20	90	LPOTW40100S	4.0	100	90
LPOTW4520S	4.5	20	90	LPOTW45100S	4.5	100	90
LPOTW5020S	5.0	20	90	LPOTW50100S	5.0	100	90
LPOTW6020S	6.0	20	90	LPOTW60100S	6.0	100	90
LPOTW7020S	7.0	20	90	LPOTW70100S	7.0	100	90
LPOTW8020S	8.0	20	90	LPOTW80100S	8.0	100	90
LPOTW2040S	2.0	40	90	LPOTW20120S	2.0	120	90
LPOTW2540S	2.5	40	90	LPOTW25120S	2.5	120	90
LPOTW3040S	3.0	40	90	LPOTW30120S	3.0	120	90
LPOTW3540S	3.5	40	90	LPOTW35120S	3.5	120	90





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LPOTW4040S	4.0	40	90	LPOTW40120S	4.0	120	90
LPOTW4540S	4.5	40	90	LPOTW45120S	4.5	120	90
LPOTW5040S	5.0	40	90	LPOTW50120S	5.0	120	90
LPOTW6040S	6.0	40	90	LPOTW60120S	6.0	120	90
LPOTW7040S	7.0	40	90	LPOTW70120S	7.0	120	90
LPOTW8040S	8.0	40	90	LPOTW80120S	8.0	120	90
LPOTW2060S	2.0	60	90	LPOTW20150S	2.0	150	90
LPOTW2560S	2.5	60	90	LPOTW25150S	2.5	150	90
LPOTW3060S	3.0	60	90	LPOTW30150S	3.0	150	90
LPOTW3560S	3.5	60	90	LPOTW35150S	3.5	150	90
LPOTW4060S	4.0	60	90	LPOTW40150S	4.0	150	90
LPOTW4560S	4.5	60	90	LPOTW45150S	4.5	150	90
LPOTW5060S	5.0	60	90	LPOTW50150S	5.0	150	90
LPOTW6060S	6.0	60	90	LPOTW60150S	6.0	150	90
LPOTW7060S	7.0	60	90	LPOTW70150S	7.0	150	90
LPOTW8060S	8.0	60	90	LPOTW80150S	8.0	150	90
LPOTW2080S	2.0	80	90	LPOTW20220S	2.0	220	90
LPOTW2580S	2.5	80	90	LPOTW25220S	2.5	220	90
LPOTW3080S	3.0	80	90	LPOTW30220S	3.0	220	90
LPOTW3580S	3.5	80	90	LPOTW35220S	3.5	220	90
LPOTW4080S	4.0	80	90	LPOTW40220S	4.0	220	90
LPOTW4580S	4.5	80	90	LPOTW45220S	4.5	220	90
LPOTW5080S	5.0	80	90	LPOTW50220S	5.0	220	90
LPOTW6080S	6.0	80	90	LPOTW60220S	6.0	220	90
LPOTW7080S	7.0	80	90	LPOTW70220S	7.0	220	90
LPOTW8080S	8.0	80	90	LPOTW80220S	8.0	220	90

OTW Drug-Released Balloons with 0.018 "Guidewire (Catheter: 120 cm)							
Reference No	Balloon diameter (mm)	Balloon length (mm)	Catheter Shaft length (cm)	Reference No	Balloon diameter (mm)	Balloon length (mm)	Catheter Shaft length (cm)
LPOTW2020M	2.0	20	120	LPOTW20100M	2.0	100	120
LPOTW2520M	2.5	20	120	LPOTW25100M	2.5	100	120
LPOTW3020M	3.0	20	120	LPOTW30100M	3.0	100	120
LPOTW3520M	3.5	20	120	LPOTW35100M	3.5	100	120
LPOTW4020M	4.0	20	120	LPOTW40100M	4.0	100	120
LPOTW4520M	4.5	20	120	LPOTW45100M	4.5	100	120
LPOTW5020M	5.0	20	120	LPOTW50100M	5.0	100	120
LPOTW6020M	6.0	20	120	LPOTW60100M	6.0	100	120
LPOTW7020M	7.0	20	120	LPOTW70100M	7.0	100	120
LPOTW8020M	8.0	20	120	LPOTW80100M	8.0	100	120
LPOTW2040M	2.0	40	120	LPOTW20120M	2.0	120	120
LPOTW2540M	2.5	40	120	LPOTW25120M	2.5	120	120
LPOTW3040M	3.0	40	120	LPOTW30120M	3.0	120	120
LPOTW3540M	3.5	40	120	LPOTW35120M	3.5	120	120
LPOTW4040M	4.0	40	120	LPOTW40120M	4.0	120	120
LPOTW4540M	4.5	40	120	LPOTW45120M	4.5	120	120
LPOTW5040M	5.0	40	120	LPOTW50120M	5.0	120	120

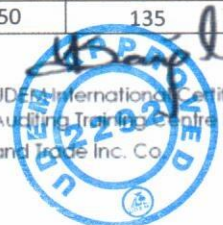




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LPOTW6040M	6.0	40	120	LPOTW60120M	6.0	120	120
LPOTW7040M	7.0	40	120	LPOTW70120M	7.0	120	120
LPOTW8040M	8.0	40	120	LPOTW80120M	8.0	120	120
LPOTW2060M	2.0	60	120	LPOTW20150M	2.0	150	120
LPOTW2560M	2.5	60	120	LPOTW25150M	2.5	150	120
LPOTW3060M	3.0	60	120	LPOTW30150M	3.0	150	120
LPOTW3560M	3.5	60	120	LPOTW35150M	3.5	150	120
LPOTW4060M	4.0	60	120	LPOTW40150M	4.0	150	120
LPOTW4560M	4.5	60	120	LPOTW45150M	4.5	150	120
LPOTW5060M	5.0	60	120	LPOTW50150M	5.0	150	120
LPOTW6060M	6.0	60	120	LPOTW60150M	6.0	150	120
LPOTW7060M	7.0	60	120	LPOTW70150M	7.0	150	120
LPOTW8060M	8.0	60	120	LPOTW80150M	8.0	150	120
LPOTW2080M	2.0	80	120	LPOTW20220M	2.0	220	120
LPOTW2580M	2.5	80	120	LPOTW25220M	2.5	220	120
LPOTW3080M	3.0	80	120	LPOTW30220M	3.0	220	120
LPOTW3580M	3.5	80	120	LPOTW35220M	3.5	220	120
LPOTW4080M	4.0	80	120	LPOTW40220M	4.0	220	120
LPOTW4580M	4.5	80	120	LPOTW45220M	4.5	220	120
LPOTW5080M	5.0	80	120	LPOTW50220M	5.0	220	120
LPOTW6080M	6.0	80	120	LPOTW60220M	6.0	220	120
LPOTW7080M	7.0	80	120	LPOTW70220M	7.0	220	120
LPOTW8080M	8.0	80	120	LPOTW80220M	8.0	220	120

OTW Drug-Released Balloons with 0.018 "Guidewire (catheter length: 135cm)							
Reference No	Balloon diameter (mm)	Balloon length (mm)	Catheter Shaft length (cm)	Reference No	Balloon diameter (mm)	Balloon length (mm)	Catheter Shaft length (cm)
LPOTW2020L	2.0	20	135	LPOTW20100L	2.0	100	135
LPOTW2520L	2.5	20	135	LPOTW25100L	2.5	100	135
LPOTW3020L	3.0	20	135	LPOTW30100L	3.0	100	135
LPOTW3520L	3.5	20	135	LPOTW35100L	3.5	100	135
LPOTW4020L	4.0	20	135	LPOTW40100L	4.0	100	135
LPOTW4520L	4.5	20	135	LPOTW45100L	4.5	100	135
LPOTW5020L	5.0	20	135	LPOTW50100L	5.0	100	135
LPOTW6020L	6.0	20	135	LPOTW60100L	6.0	100	135
LPOTW7020L	7.0	20	135	LPOTW20120L	2.0	120	135
LPOTW8020L	8.0	20	135	LPOTW25120L	2.5	120	135
LPOTW2040L	2.0	40	135	LPOTW30120L	3.0	120	135
LPOTW2540L	2.5	40	135	LPOTW35120L	3.5	120	135
LPOTW3040L	3.0	40	135	LPOTW40120L	4.0	120	135
LPOTW3540L	3.5	40	135	LPOTW45120L	4.5	120	135
LPOTW4040L	4.0	40	135	LPOTW50120L	5.0	120	135
LPOTW4540L	4.5	40	135	LPOTW60120L	6.0	120	135
LPOTW5040L	5.0	40	135	LPOTW20150L	2.0	150	135
LPOTW6040L	6.0	40	135	LPOTW25150L	2.5	150	135
LPOTW7040L	7.0	40	135	LPOTW30150L	3.0	150	135





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LPOTW8040L	8.0	40	135	LPOTW35150L	3.5	150	135
LPOTW2060L	2.0	60	135	LPOTW40150L	4.0	150	135
LPOTW2560 L	2.5	60	135	LPOTW45150L	4.5	150	135
LPOTW3060L	3.0	60	135	LPOTW50150L	5.0	150	135
LPOTW3560L	3.5	60	135	LPOTW60150L	6.0	150	135
LPOTW4060L	4.0	60	135	LPOTW20220L	2.0	220	135
LPOTW4560L	4.5	60	135	LPOTW25220L	2.5	220	135
LPOTW5060L	5.0	60	135	LPOTW30220L	3.0	220	135
LPOTW6060L	6.0	60	135	LPOTW35220L	3.5	220	135
LPOTW7060L	7.0	60	135	LPOTW40220L	4.0	220	135
LPOTW8060L	8.0	60	135	LPOTW45220L	4.5	220	135
LPOTW2080L	2.0	80	135	LPOTW50220L	5.0	220	135
LPOTW2580L	2.5	80	135	LPOTW60220L	6.0	220	135
LPOTW3080 L	3.0	80	135				
LPOTW3580L	3.5	80	135				
LPOTW4080L	4.0	80	135				
LPOTW4580L	4.5	80	135				
LPOTW5080L	5.0	80	135				
LPOTW6080L	6.0	80	135				

OTW Drug-Released Balloons with 0.035 "Guidewire (Catheter Shaft: 80 cm)							
Reference No	Balloon diameter (mm)	Balloon length (mm)	Catheter Shaft length (cm)	Reference No	Balloon diameter (mm)	Balloon length (mm)	Catheter Shaft length (cm)
TER320S	3,0	20	80 cm	TER3100S	3,0	100	80 cm
TER420S	4.0	20	80 cm	TER41000S	4.0	100	80 cm
TER4520S	4.5	20	80 cm	TER45100S	4.5	100	80 cm
TER520S	5.0	20	80 cm	TER5100S	5.0	100	80 cm
TER5520S	5.5	20	80 cm	TER55100S	5.5	100	80 cm
TER620S	6.0	20	80 cm	TER6100S	6.0	100	80 cm
TER6520S	6.5	20	80 cm	TER65100S	6.5	100	80 cm
TER720S	7.0	20	80 cm	TER7100S	7.0	100	80 cm
TER820S	8.0	20	80 cm	TER8100S	8.0	100	80 cm
TER340S	3,0	40	80 cm	TER3120S	3.0	120	80 cm
TER440S	4.0	40	80 cm	TER4120S	4.0	120	80 cm
TER540S	5.0	40	80 cm	TER45120S	4.5	120	80 cm
TER5540S	5.5	40	80 cm	TER5120S	5.0	120	80 cm
TER640S	6.0	40	80 cm	TER55120S	5.5	120	80 cm
TER6540S	6.5	40	80 cm	TER6120S	6.0	120	80 cm
TER740S	7.0	40	80 cm	TER65120S	6.5	120	80 cm
TER840S	8.0	40	80 cm	TER7120S	7.0	120	80 cm
TER360S	3,0	60	80 cm	TER8120S	8.0	120	80 cm
TER460S	4.0	60	80 cm	TER3150S	3,0	150	80 cm
TER4560S	4.5	60	80 cm	TER4150S	4.0	150	80 cm





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TER560S	5.0	60	80 cm	TER45150S	4.5	150	80 cm
TER5560S	5.5	60	80 cm	TER5150S	5.0	150	80 cm
TER660S	6.0	60	80 cm	TER55150S	5.5	150	80 cm
TER660S	6.5	60	80 cm	TER6150S	6.0	150	80 cm
TER760S	7.0	60	80 cm	TER65150S	6.5	150	80 cm
TER860S	8.0	60	80 cm	TER7150S	7.0	150	80 cm
TER340S	3,0	80	80 cm	TER8150S	8.0	150	80 cm
TER440S	4.0	80	80 cm	TER300S	3.0	200	80 cm
TER4540S	4.5	80	80 cm	TER4200S	4.0	200	80 cm
TER540S	5.0	80	80 cm	TER45200S	4.5	200	80 cm
TER5540S	5.5	80	80 cm	TER5200S	5.0	200	80 cm
TER640S	6.0	80	80 cm	TER55200S	5.5	200	80 cm
TER6540S	6.5	80	80 cm	TER6200S	6.0	200	80 cm
TER740S	7.0	80	80 cm	TER65200S	6.5	200	80 cm
TER840S	8.0	80	80 cm	TER7200S	7.0	200	80 cm
				TER8200S	8.0	200	80 cm

OTW Drug-Released Balloons with 0.035 "Guidewire (Catheter Shaft: 135 cm)

Reference No	Balloon diameter (mm)	Balloon length (mm)	Catheter Shaft length (cm)	Reference No	Balloon diameter (mm)	Balloon length (mm)	Catheter Shaft length (cm)
TER320L	3,0	20	135	TER3100L	3,0	100	135
TER420L	4.0	20	135	TER4100L	4.0	100	135
TER4520L	4.5	20	135	TER45100L	4.5	100	135
TER520L	5.0	20	135	TER5100L	5.0	100	135
TER5520L	5.5	20	135	TER55100L	5.5	100	135
TER620L	6.0	20	135	TER6100L	6.0	100	135
TER6520L	6.5	20	135	TER65100L	6.5	100	135
TER720L	7.0	20	135	TER7100L	7.0	100	135
TER820L	8.0	20	135	TER8100L	8.0	100	135
TER340L	3,0	40	135	TER9100L	9.0	100	135
TER440L	4.0	40	135	TER10100L	10.0	100	135
TER4540L	4.5	40	135	TER12100L	12.0	100	135
TER540L	5.0	40	135	TER3120L	3.0	120	135
TER5540L	5.5	40	135	TER4120L	4.0	120	135
TER640L	6.0	40	135	TER45120L	4.5	120	135
TER6540L	6.5	40	135	TER5120L	5.0	120	135
TER740L	7.0	40	135	TER55120L	5.5	120	135
TER840L	8.0	40	135	TER6120L	6.0	120	135
TER360L	3,0	60	135	TER65120L	6.5	120	135
TER460L	4.0	60	135	TER7120L	7.0	120	135
TER4560L	4.5	60	135	TER8120L	8.0	120	135
TER560L	5.0	60	135	TER9120L	9.0	120	135
TER5560L	5.5	60	135	TER10120L	10.0	120	135
TER660L	6.0	60	135	TER3150L	3,0	150	135
TER6560L	6.5	60	135	TER4150L	4.0	150	135
TER760L	7.0	60	135	TER45150L	4.5	150	135
TER860L	8.0	60	135	TER5150L	5.0	150	135
TER960L	9.0	60	135	TER55150L	5.5	150	135





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TER1060L	10.0	60	135	TER6150L	6.0	150	135
TER380L	3.0	80	135	TER65150L	6.5	150	135
TER480L	4.0	80	135	TER7150L	7.0	150	135
TER4580L	4.5	80	135	TER8150L	8.0	150	135
TER580L	5.0	80	135	TER9150L	9.0	150	135
TER5580L	5.5	80	135	TER10150L	10.0	150	135
TER680L	6.0	80	135	TER3200L	3.0	200	135
TER6580L	6.5	80	135	TER4200L	4.0	200	135
TER780L	7.0	80	135	TER45200L	4.5	200	135
TER880L	8.0	80	135	TER5200L	5.0	200	135
TER980L	9.0	80	135	TER55200L	5.5	200	135
TER1080L	10.0	80	135	TER6200L	6.0	200	135
TER1280L	12.0	80	135	TER65200L	6.5	200	135
				TER7200L	7.0	200	135
				TER8200L	8.0	200	135

RX Drug-Released Balloons with 0.014 "Guidewire (Catheter Shaft: 120 cm)				RX Drug-Released Balloons with 0.014 "Guidewire (Catheter Shaft: 150 cm)			
Reference No	Balloon diameter (mm)	Balloon length (mm)	Catheter Shaft length (cm)	Reference No	Balloon diameter (mm)	Balloon length (mm)	Catheter Shaft length (cm)
LPRX2010M	2.0	10	120	LPRX2010X	2.0	10	150
LPRX2510M	2.5	10	120	LPRX2510X	2.5	10	150
LPRX27510M	2.75	10	120	LPRX27510X	2.75	10	150
LPRX3010M	3.0	10	120	LPRX3010X	3.0	10	150
LPRX3510M	3.5	10	120	LPRX3510X	3.5	10	150
LPRX4010M	4.0	10	120	LPRX4010X	4.0	10	150
LPRX2015M	2.0	15	120	LPRX2015X	2.0	15	150
LPRX2515M	2.5	15	120	LPRX2515X	2.5	15	150
LPRX27515M	2.75	15	120	LPRX27515X	2.75	15	150
LPRX3015M	3.0	15	120	LPRX3015X	3.0	15	150
LPRX3515M	3.5	15	120	LPRX3515X	3.5	15	150
LPRX4015M	4.0	15	120	LPRX4015X	4.0	15	150
LPRX2017M	2.0	17	120	LPRX2017X	2.0	17	150
LPRX2517M	2.5	17	120	LPRX2517X	2.5	17	150
LPRX27517M	2.75	17	120	LPRX27517X	2.75	17	150
LPRX3017M	3.0	17	120	LPRX3017X	3.0	17	150
LPRX3517M	3.5	17	120	LPRX3517X	3.5	17	150
LPRX4017M	4.0	17	120	LPRX4017X	4.0	17	150
LPRX2020M	2.0	20	120	LPRX2020X	2.0	20	150
LPRX2520M	2.5	20	120	LPRX2520X	2.5	20	150
LPRX27520M	2.75	20	120	LPRX27520X	2.75	20	150
LPRX3020M	3.0	20	120	LPRX3020X	3.0	20	150
LPRX3520M	3.5	20	120	LPRX3520X	3.5	20	150
LPRX4020M	4.0	20	120	LPRX4020X	4.0	20	150





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LPRX2026M	2,0	26	120	LPRX2026X	2,0	26	150
LPRX2526M	2,5	26	120	LPRX2526X	2,5	26	150
LPRX27526M	2.75	26	120	LPRX27526X	2.75	26	150
LPRX3026M	3.0	26	120	LPRX3026X	3.0	26	150
LPRX3526M	3.5	26	120	LPRX3526X	3.5	26	150
LPRX4026M	4.0	26	120	LPRX4026X	4.0	26	150
LPRX2030M	2,0	30	120	LPRX2030X	2,0	30	150
LPRX2530M	2,5	30	120	LPRX2530X	2,5	30	150
LPRX27530M	2.75	30	120	LPRX27530X	2.75	30	150
LPRX3030M	3.0	30	120	LPRX3030X	3.0	30	150
LPRX3530M	3.5	30	120	LPRX3530X	3.5	30	150
LPRX4030M	4.0	30	120	LPRX4030X	4.0	30	150

Identification of the Legal Manufacturer:



Invamed Sağlık İlaç San. Ve Tic. A.Ş.

Malıköy Anadolu OSB 30 Ağustos Cad. No:13
Sincan ANKARA/TURKEY

This Declaration of Conformity is issued under the sole responsibility of the Invamed Sağlık İlaç San. Ve Tic. A.Ş.

Identification of the device(s) concerned:

✓ Atlas Peripheral Stent System – Class IIb, Sterile

Risk Classification:

Class IIb as per Rule 8 in Annex IX

Product	RULE	CLASS	GMDN
Atlas Peripheral Stent System	RULE 8	Class IIb	47932

We hereby confirm that these products, which are our sales and responsibility, comply with all applicable requirements of the EU Directive 93/42 / EEC of 14 July 1993 (including revision 2007/47 / EC) and the requirements of the relevant harmonized standards. All supporting documentation is maintained at the premises of INVAMED. The declaration of conformity states that medical devices which correspond to all product model numbers specified in the annex are produced by INVAMED and are included in the certified Quality System Documentation. INVAMED declares that the Quality System will meet its requirements and will continue to maintain its quality system in full and effective.

Relevant Harmonized Standards

ASTM F 1980, TS EN ISO 10993-1, TS EN ISO 10993-2, TS EN ISO 10993-4, TS EN ISO 10993-5, TS EN ISO 10993-6, TS EN ISO 10993-7, TS EN ISO 10993-7 /AC, TS EN ISO 10993-10, TS EN ISO 10993-11, TS EN ISO 10993-12, S EN ISO 14644-1, TS EN ISO 14644-2, TS EN ISO 14644-3, TS EN ISO 14644-4, TS EN ISO 14644-5, TS EN ISO 14644-7, TS EN ISO 14644-8, TS EN ISO 11607-1, TS EN ISO 11607-1/A1, TS EN ISO 11607-2, TS EN ISO 11607-2/A1, TS EN ISO 16061, TS EN ISO 25539-2: 2009, TS EN ISO 14630, ASTM F2063-05, ASTM F2129-08, ASTM F138, ASTM F139, ASTM F560-4, Blue Guide, MDR Medical Device Regulation, TS EN ISO 10555-1, TS EN ISO 10555-1/A1, TS EN 1041+A1, TS EN ISO 13485, TS EN ISO 13485/AC, TS EN ISO 14698-2/AC, 93/42/EEC, TS EN ISO 14937, TS EN ISO 11138-2, TS EN ISO/IEC 17050-1, TS EN ISO/IEC 17050-2, TS EN ISO 15223-1, TS EN 556-1, TS EN ISO 11737-1, TS EN ISO 11737-1/AC, TS EN 62366-1, TS EN 62366-1 /AC, TS EN ISO 14971 , TS EN ISO

11070, TS EN 11135, MEDDEV 2.12.2, MEDDEV 2.4.1, MEDDEV 2.5/5, MEDDEV 2.7.1. rev4, MEDDEV 2.12.1, TS EN ISO 12417-1.

Name and address of Notified Body:

UDEM Uluslararası Belgelendirme Denetim Eğitim Ltd. Şti.
Onaylanmış Kuruluş No: 2292
Mutlukent Mah. 2073 Sk. No:10
Ümitköy - Çankaya - ANKARA

Applicable CE Certificate(s):

EC Quality System Certificate No. CE M.2020.106.13847, issued by the UDEM Notified Body Number 2292, in accordance with Annex II excluding Section 4 of this Directive.

Date of CE Marking :

28.08.2020

Name: İlker Cömertoğlu
Title: General Manager

Identification of the person authorized to sign on behalf of Invamed A.Ş.:



Signature: _____

Place of Issue: Ankara, TURKIYE
Date: 02.07.2020



DECLARATION OF CONFORMITY

REVISION: 01/02.07.2020
DOC. NO: Tek.Dos.08-15
DATE OF ISSUE: 02.11.2015
PAGE: 3 of 5

	Product List	GMDN
REF NO	Product Name	
ATS-05-020-6F-80	Atlas Peripheral Stent System 5mm*20mm*80cm, 6F	47932
ATS-05-020-6F-120	Atlas Peripheral Stent System 5mm*20mm*120cm, 6F	47932
ATS-05-040-6F-80	Atlas Peripheral Stent System 5mm*40mm*80cm, 6F	47932
ATS-05-040-6F-120	Atlas Peripheral Stent System 5mm*40mm*120cm, 6F	47932
ATS-05-060-6F-80	Atlas Peripheral Stent System 5mm*60mm*80cm, 6F	47932
ATS-05-060-6F-120	Atlas Peripheral Stent System 5mm*60mm*120cm, 6F	47932
ATS-05-080-6F-80	Atlas Peripheral Stent System 5mm*80mm*80cm, 6F	47932
ATS-05-080-6F-120	Atlas Peripheral Stent System 5mm*80mm*120cm, 6F	47932
ATS-05-100-6F-80	Atlas Peripheral Stent System 5mm*100mm*80cm, 6F	47932
ATS-05-100-6F-120	Atlas Peripheral Stent System 5mm*100mm*120cm, 6F	47932
ATS-05-120-6F-80	Atlas Peripheral Stent System 5mm*120mm*80cm, 6F	47932
ATS-05-120-6F-120	Atlas Peripheral Stent System 5mm*120mm*120cm, 6F	47932
ATS-05-150-6F-80	Atlas Peripheral Stent System 5mm*150mm*80cm, 6F	47932
ATS-05-150-6F-120	Atlas Peripheral Stent System 5mm*150mm*120cm, 6F	47932
ATS-06-020-6F-80	Atlas Peripheral Stent System 6mm*20mm*80cm, 6F	47932
ATS-06-020-6F-120	Atlas Peripheral Stent System 6mm*20mm*120cm, 6F	47932
ATS-06-030-6F-80	Atlas Peripheral Stent System 6mm*30mm*80cm, 6F	47932
ATS-06-030-6F-120	Atlas Peripheral Stent System 6mm*30mm*120cm, 6F	47932
ATS-06-040-6F-80	Atlas Peripheral Stent System 6mm*40mm*80cm, 6F	47932
ATS-06-040-6F-120	Atlas Peripheral Stent System 6mm*40mm*120cm, 6F	47932
ATS-06-060-6F-80	Atlas Peripheral Stent System 6mm*60mm*80cm, 6F	47932
ATS-06-060-6F-120	Atlas Peripheral Stent System 6mm*60mm*120cm, 6F	47932
ATS-06-080-6F-80	Atlas Peripheral Stent System 6mm*80mm*80cm, 6F	47932
ATS-06-080-6F-120	Atlas Peripheral Stent System 6mm*80mm*120cm, 6F	47932
ATS-06-100-6F-80	Atlas Peripheral Stent System 6mm*100mm*80cm, 6F	47932
ATS-06-100-6F-120	Atlas Peripheral Stent System 6mm*100mm*120cm, 6F	47932
ATS-06-120-6F-80	Atlas Peripheral Stent System 6mm*120mm*80cm, 6F	47932
ATS-06-120-6F-120	Atlas Peripheral Stent System 6mm*120mm*120cm, 6F	47932
ATS-06-150-6F-80	Atlas Peripheral Stent System 6mm*150mm*80cm, 6F	47932
ATS-06-150-6F-120	Atlas Peripheral Stent System 6mm*150mm*120cm, 6F	47932



DECLARATION OF CONFORMITY

REVISION: 01/02.07.2020
DOC. NO: Tek.Dos.08-15
DATE OF ISSUE: 02.11.2015
PAGE: 4 of 5

	Product List	GMDN
REF NO	Product Name	
ATS-06-200-6F-120	Atlas Peripheral Stent System 6mm*200mm*120cm, 6F	47932
ATS-07-020-6F-80	Atlas Peripheral Stent System 7mm*20mm*80cm, 6F	47932
ATS-07-020-6F-120	Atlas Peripheral Stent System 7mm*20mm*120cm, 6F	47932
ATS-07-020-6F-80	Atlas Peripheral Stent System 7mm*20mm*80cm, 6F	47932
ATS-07-020-6F-120	Atlas Peripheral Stent System 7mm*20mm*120cm, 6F	47932
ATS-07-030-6F-80	Atlas Peripheral Stent System 7mm*30mm*80cm, 6F	47932
ATS-07-030-6F-120	Atlas Peripheral Stent System 7mm*30mm*120cm, 6F	47932
ATS-07-040-6F-80	Atlas Peripheral Stent System 7mm*40mm*80cm, 6F	47932
ATS-07-040-6F-120	Atlas Peripheral Stent System 7mm*40mm*120cm, 6F	47932
ATS-07-060-6F-80	Atlas Peripheral Stent System 7mm*60mm*80cm, 6F	47932
ATS-07-060-6F-120	Atlas Peripheral Stent System 7mm*60mm*120cm, 6F	47932
ATS-07-080-6F-80	Atlas Peripheral Stent System 7mm*80mm*80cm, 6F	47932
ATS-07-080-6F-120	Atlas Peripheral Stent System 7mm*80mm*120cm, 6F	47932
ATS-07-100-6F-80	Atlas Peripheral Stent System 7mm*100mm*80cm, 6F	47932
ATS-07-100-6F-120	Atlas Peripheral Stent System 7mm*100mm*120cm, 6F	47932
ATS-07-120-6F-80	Atlas Peripheral Stent System 7mm*120mm*80cm, 6F	47932
ATS-07-120-6F-120	Atlas Peripheral Stent System 7mm*120mm*120cm, 6F	47932
ATS-07-150-6F-80	Atlas Peripheral Stent System 7mm*150mm*80cm, 6F	47932
ATS-07-150-6F-120	Atlas Peripheral Stent System 7mm*150mm*120cm, 6F	47932
ATS-07-200-6F-120	Atlas Peripheral Stent System 7mm*200mm*120cm, 6F	47932
ATS-08-020-6F-80	Atlas Peripheral Stent System 8mm*20mm*80cm, 6F	47932
ATS-08-020-6F-120	Atlas Peripheral Stent System 8mm*20mm*120cm, 6F	47932
ATS-08-030-6F-80	Atlas Peripheral Stent System 8mm*30mm*80cm, 6F	47932
ATS-08-030-6F-120	Atlas Peripheral Stent System 8mm*30mm*120cm, 6F	47932
ATS-08-040-6F-80	Atlas Peripheral Stent System 8mm*40mm*80cm, 6F	47932
ATS-08-040-6F-120	Atlas Peripheral Stent System 8mm*40mm*120cm, 6F	47932
ATS-08-060-6F-80	Atlas Peripheral Stent System 8mm*60mm*80cm, 6F	47932
ATS-08-060-6F-120	Atlas Peripheral Stent System 8mm*60mm*120cm, 6F	47932
ATS-08-080-6F-80	Atlas Peripheral Stent System 8mm*80mm*80cm, 6F	47932
ATS-08-080-6F-120	Atlas Peripheral Stent System 8mm*80mm*120cm, 6F	47932



DECLARATION OF CONFORMITY

REVISION: 01/02.07.2020
DOC. NO: Tek.Dos.08-15
DATE OF ISSUE: 02.11.2015
PAGE: 5 of 5

	Product List	GMDN
REF NO	Product Name	
ATS-08-100-6F-80	Atlas Peripheral Stent System 8mm*100mm*80cm, 6F	47932
ATS-08-100-6F-120	Atlas Peripheral Stent System 8mm*100mm*120cm, 6F	47932
ATS-08-120-6F-80	Atlas Peripheral Stent System 8mm*120mm*80cm, 6F	47932
ATS-08-120-6F-120	Atlas Peripheral Stent System 8mm*120mm*120cm, 6F	47932
ATS-08-150-6F-80	Atlas Peripheral Stent System 8mm*150mm*80cm, 6F	47932
ATS-08-150-6F-120	Atlas Peripheral Stent System 8mm*150mm*120cm, 6F	47932
ATS-08-200-6F-120	Atlas Peripheral Stent System 8mm*200mm*120cm, 6F	47932



AT S E R T İ F İ K A

Tam Kalite Güvence Sistemi

93/42/AT Tıbbi Cihazlar Direktifi Ek II (Madde 4 Hariç)

Firma Adı : Prosim Sağlık Anonim Şirketi

Firma Adresi : Kültür Mah. Ahmet Adnan Saygun Cad. Akmerkez Blok No:3
İç Kapı No:536 Beşiktaş İSTANBUL / TÜRKİYE

Üretim Adresi : Alçı Osb Mah. 2010 Cad.No:4 İç Kapı No:0 Sincan ANKARA / TÜRKİYE

İlgili Yönetmelikler ve Ekler : 93/42/AT Tıbbi Cihazlar Yönetmeliği - Ek II (Madde 4 Hariç)

Ürünler : Non-Steril Sabitleme (Fiksasyon) Zımbaları - Sınıf IIb
Non-Steril Ulna Çivileri - Sınıf IIb
Non-Steril Femur Çivileri - Sınıf IIb
Non-Steril Humerus Çivileri - Sınıf IIb
Non-Steril Tibia Çivileri - Sınıf IIb
Non-Steril Elastik Çiviler - Sınıf IIb
Ortopedik Fiksasyon Plakaları, Biyobozunur Olmayan, Non Steril - Sınıf IIb
Ortopedik Kemik Vidaları, Biyobozunur Olmayan, Non Steril - Sınıf IIb

GMDN : 35615, 47762, 56643, 56644, 56645, 61154, 61573, 56642

Ürün Çeşitleri Ek'tedir.

Sertifika Numarası : M.2021.106.14494

Rapor Numarası : MD.4224.IB

İlk Belgelendirme Denetimi : 21.11.2020

Tescil Tarihi : 27.04.2021

Revizyon Tarihi/No : -

Geçerlilik Tarihi : 27.05.2024



UDEM Uluslararası Belgelendirme
Denetim Eğitim Merkezi
San. ve Tic. A.Ş.

UDEM, listeli ürünlerin 93/42/AT direktifi Ek II, madde 4 hariç gerekliliklerinin karşıladığını beyan eder. Yukarıda adı geçen üretici Kalite Güvence Sistemi uyguladığını ve Ek II madde 5'e göre periyodik gözetim denetimleri ile sürekliliğini sağlayacağını beyan eder. Sınıf III olarak piyasaya arz edilecek ürünler için Ek II madde 4'e göre AT Tasarım İnceleme sertifikası gereklidir. Belge kapsamında yer alan sınıf I ürünler ile ilgili UDEM'in sorumluluğu ürün steril ise, steril şartların güvence altına alınması ve sürdürülmesi ile ilgili imalat konuları; ölçüm fonksiyonlu ise, ürünlerin metrolojik gereklere uygunluğuyla ilgili imalat konuları ile sınırlıdır. Bu belgenin mükiyet hakkı UDEM Uluslararası Belgelendirme Denetim Eğitim San. ve Tic. A.Ş.'ye aittir ve istenildiğinde iade edilmelidir. Yukarıda adı geçen firma ve UDEM bu belgenin bir kopyasını Tescil tarihinden itibaren 5 yıl süre ile muhafaza etmektedir. CE Markalamanın kullanımı üretici beyanıyla firma sorumluluğundadır. Adı geçen firma onaylanmış ürün ile ilgili bütün değişiklikleri UDEM'e bildirmek zorundadır. UDEM bu belgenin geçerliliğini yenilemezse adı geçen firma söz konusu ürünün piyasaya arzını durduracaktır. Belgenin geçerliliğini www.udem.com.tr internet sayfasından kontrol edebilirsiniz.



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UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş. 2292 Kimlik Numarası ile 93/42/EEC Tıbbi Cihazlar Yönetmeliği'nde Onaylanmış Kuruluş olarak faaliyet göstermekte olup, Bu yedi sayfalık doküman "Prosim Sağlık Anonim Şirketi" firmasına düzenlenmiş olan 27.04.2021 Tescil Tarihli M.2021.106.14494 Numaralı Belge'nin Eki'dir.

ÜRÜN ADI	GMDN KODU
TRAVMA, PLAK (TİTANYUM), WING PLATE, VASHOLE, 07 HOLES	61573
TRAVMA, PLAK (TİTANYUM), KLAVİKULA, KANCALI, SOL, SECURELOCK	61573
TRAVMA, PLAK (TİTANYUM), KLAVİKULA, KANCALI, SAĞ, SECURELOCK	61573
TRAVMA, PLAK (TİTANYUM), KLAVİKULA, KANCALI, SOL, COMBİHOLE	61573
TRAVMA, PLAK (TİTANYUM), KLAVİKULA, KANCALI, SAĞ, COMBİHOLE	61573
TRAVMA, PLAK (TİTANYUM), KLAVİKULA, KANCALI, SOL, VASHOLE	61573
TRAVMA, PLAK (TİTANYUM), KLAVİKULA, KANCALI, SAĞ, VASHOLE	61573
TRAVMA, PLAK (TİTANYUM), KLAVİKULA, -S, SOL, SECURELOCK	61573
TRAVMA, PLAK (TİTANYUM), KLAVİKULA, -S, SAĞ, SECURELOCK	61573
TRAVMA, PLAK (TİTANYUM), KLAVİKULA, -S, SOL, COMBİHOLE	61573
TRAVMA, PLAK (TİTANYUM), KLAVİKULA, -S, SAĞ, COMBİHOLE	61573
TRAVMA, PLAK (TİTANYUM), KLAVİKULA, -S, SOL, VASHOLE	61573
TRAVMA, PLAK (TİTANYUM), KLAVİKULA, -S, SAĞ, VASHOLE	61573
TRAVMA, PLAK (TİTANYUM), HUMERUS, PROXİMAL, COMBİHOLE	61573
TRAVMA, PLAK (TİTANYUM), HUMERUS, PROXİMAL, SECURELOCK	61573
TRAVMA, PLAK (TİTANYUM), HUMERUS, PROXİMAL, VASHOLE	61573
TRAVMA, PLAK (TİTANYUM), HUMERUS, PROXİMAL, ANATOMİK, SOL, SECURELOCK	61573
TRAVMA, PLAK (TİTANYUM), HUMERUS, PROXİMAL, ANATOMİK, SAĞ, SECURELOCK	61573
TRAVMA, PLAK (TİTANYUM), HUMERUS, PROXİMAL, ANATOMİK, SOL, COMBİHOLE	61573
TRAVMA, PLAK (TİTANYUM), HUMERUS, PROXİMAL, ANATOMİK, SAĞ, COMBİHOLE	61573
TRAVMA, PLAK (TİTANYUM), HUMERUS, PROXİMAL, ANATOMİK, SOL, VASHOLE	61573
TRAVMA, PLAK (TİTANYUM), HUMERUS, PROXİMAL, ANATOMİK, SAĞ, VASHOLE	61573
TRAVMA, PLAK (TİTANYUM), HUMERUS, DUSUK PROFİL, SECURELOCK	61573
TRAVMA, PLAK (TİTANYUM), HUMERUS, DUSUK PROFİL, COMBİHOLE	61573
TRAVMA, PLAK (TİTANYUM), HUMERUS, DUSUK PROFİL, VASHOLE	61573
TRAVMA, PLAK (TİTANYUM), HUMERUS, DİSTAL, LATERAL, SOL, SECURELOCK	61573
TRAVMA, PLAK (TİTANYUM), HUMERUS, DİSTAL, LATERAL, SAĞ, SECURELOCK	61573
TRAVMA, PLAK (TİTANYUM), HUMERUS, DİSTAL, LATERAL, SOL, COMBİHOLE	61573
TRAVMA, PLAK (TİTANYUM), HUMERUS, DİSTAL, LATERAL, SAĞ, COMBİHOLE	61573
TRAVMA, PLAK (TİTANYUM), HUMERUS, DİSTAL, LATERAL, SOL, VASHOLE	61573
TRAVMA, PLAK (TİTANYUM), HUMERUS, DİSTAL, LATERAL, SAĞ, VASHOLE	61573
TRAVMA, PLAK (TİTANYUM), HUMERUS, DİSTAL, MEDİAL, SOL, SECURELOCK	61573
TRAVMA, PLAK (TİTANYUM), HUMERUS, DİSTAL, MEDİAL, SAĞ, SECURELOCK	61573
TRAVMA, PLAK (TİTANYUM), HUMERUS, DİSTAL, MEDİAL, SOL, COMBİHOLE	61573
TRAVMA, PLAK (TİTANYUM), HUMERUS, DİSTAL, MEDİAL, SAĞ, COMBİHOLE	61573
TRAVMA, PLAK (TİTANYUM), HUMERUS, DİSTAL, MEDİAL, SOL, VASHOLE	61573
TRAVMA, PLAK (TİTANYUM), HUMERUS, DİSTAL, MEDİAL, SAĞ, VASHOLE	61573
TRAVMA, PLAK (TİTANYUM), ULNA/RADİUS, OLEKRANON, SOL, SECURELOCK	61573
TRAVMA, PLAK (TİTANYUM), ULNA/RADİUS, OLEKRANON, SAĞ, SECURELOCK	61573
TRAVMA, PLAK (TİTANYUM), ULNA/RADİUS, OLEKRANON, SOL, COMBİHOLE	61573
TRAVMA, PLAK (TİTANYUM), ULNA/RADİUS, OLEKRANON, SAĞ, COMBİHOLE	61573
TRAVMA, PLAK (TİTANYUM), ULNA/RADİUS, OLEKRANON, SOL, VASHOLE	61573
TRAVMA, PLAK (TİTANYUM), ULNA/RADİUS, OLEKRANON, SAĞ, VASHOLE	61573
TRAVMA, PLAK (TİTANYUM), ULNA / RADİUS, 1/3 TUBULAR, SECURELOCK	61573
TRAVMA, PLAK (TİTANYUM), ULNA / RADİUS, 1/3 TUBULAR, COMBİHOLE	61573
TRAVMA, PLAK (TİTANYUM), ULNA / RADİUS, 1/3 TUBULAR, VASHOLE	61573
TRAVMA, PLAK (TİTANYUM), ULNA / RADİUS, KUCUK LCP, SECURELOCK	61573
TRAVMA, PLAK (TİTANYUM), ULNA / RADİUS, KUCUK LCP, COMBİHOLE	61573
TRAVMA, PLAK (TİTANYUM), ULNA / RADİUS, KUCUK LCP, VASHOLE	61573
TRAVMA, PLAK (TİTANYUM), ULNA / RADİUS, DİSTAL, VOLAR, ACILI, SOL, SECURELOCK	61573
TRAVMA, PLAK (TİTANYUM), ULNA / RADİUS, DİSTAL, VOLAR, ACILI, SAĞ, SECURELOCK	61573
TRAVMA, PLAK (TİTANYUM), ULNA / RADİUS, DİSTAL, VOLAR, ACILI, SOL, COMBİHOLE	61573
TRAVMA, PLAK (TİTANYUM), ULNA / RADİUS, DİSTAL, VOLAR, ACILI, SAĞ, COMBİHOLE	61573
TRAVMA, PLAK (TİTANYUM), ULNA / RADİUS, DİSTAL, VOLAR, ACILI, SOL, VASHOLE	61573
TRAVMA, PLAK (TİTANYUM), ULNA / RADİUS, DİSTAL, VOLAR, ACILI, SAĞ, VASHOLE	61573
TRAVMA, PLAK (TİTANYUM), ULNA / RADİUS, DİSTAL, VOLAR, EXTRAARTİKULER, SOL, SECURELOCK	61573
TRAVMA, PLAK (TİTANYUM), ULNA / RADİUS, DİSTAL, VOLAR, EXTRAARTİKULER, SAĞ, SECURELOCK	61573
TRAVMA, PLAK (TİTANYUM), ULNA / RADİUS, DİSTAL, VOLAR, EXTRAARTİKULER, SOL, COMBİHOLE	61573
TRAVMA, PLAK (TİTANYUM), ULNA / RADİUS, DİSTAL, VOLAR, EXTRAARTİKULER, SAĞ, COMBİHOLE	61573
TRAVMA, PLAK (TİTANYUM), ULNA / RADİUS, DİSTAL, VOLAR, EXTRAARTİKULER, SOL, VASHOLE	61573
TRAVMA, PLAK (TİTANYUM), ULNA / RADİUS, DİSTAL, VOLAR, EXTRAARTİKULER, SAĞ, VASHOLE	61573
TRAVMA, PLAK (TİTANYUM), ULNA / RADİUS, DİSTAL, DORSAL, DUZ, SOL, SECURELOCK	61573
TRAVMA, PLAK (TİTANYUM), ULNA / RADİUS, DİSTAL, DORSAL, DUZ, SAĞ, SECURELOCK	61573
TRAVMA, PLAK (TİTANYUM), ULNA / RADİUS, DİSTAL, DORSAL, DUZ, SOL, COMBİHOLE	61573
TRAVMA, PLAK (TİTANYUM), ULNA / RADİUS, DİSTAL, DORSAL, DUZ, SAĞ, COMBİHOLE	61573
TRAVMA, PLAK (TİTANYUM), ULNA / RADİUS, DİSTAL, DORSAL, DUZ, SOL, VASHOLE	61573
TRAVMA, PLAK (TİTANYUM), ULNA / RADİUS, DİSTAL, DORSAL, DUZ, SAĞ, VASHOLE	61573
TRAVMA, PLAK (TİTANYUM), ULNA/RADİUS, DİSTAL, DORSAL, ACILI, SOL, SECURELOCK	61573
TRAVMA, PLAK (TİTANYUM), ULNA/RADİUS, DİSTAL, DORSAL, ACILI, SAĞ, SECURELOCK	61573
TRAVMA, PLAK (TİTANYUM), ULNA/RADİUS, DİSTAL, DORSAL, ACILI, SOL, COMBİHOLE	61573
TRAVMA, PLAK (TİTANYUM), ULNA/RADİUS, DİSTAL, DORSAL, ACILI, SAĞ, COMBİHOLE	61573
TRAVMA, PLAK (TİTANYUM), ULNA/RADİUS, DİSTAL, DORSAL, ACILI, SOL, VASHOLE	61573
TRAVMA, PLAK (TİTANYUM), ULNA/RADİUS, DİSTAL, DORSAL, ACILI, SAĞ, VASHOLE	61573
TRAVMA, PLAK (TİTANYUM), FEMUR, DHS, COMBİHOLE	61573
TRAVMA, PLAK (TİTANYUM), FEMUR, DHS, SECURELOCK	61573



UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş. 2292 Kimlik Numarası ile 93/42/EEC Tıbbi Cihazlar Yönetmeliği'nde Onaylanmış Kuruluş olarak faaliyet göstermekte olup, Bu yedi sayfalık doküman "Prosim Sağlık Anonim Şirketi" firmasına düzenlenmiş olan 27.04.2021 Tescil Tarihli M.2021.106.14494 Numaralı Belge'nin Eki'dir.

TRAVMA, PLAK (TİTANYUM), FEMUR, DCS, SECURELOCK	61573
TRAVMA, PLAK (TİTANYUM), FEMUR, DCS, COMBIHOLE	61573
TRAVMA, PLAK (TİTANYUM), FEMUR, TROCHANTERIC STABİLİZATİON,COMBIHOLE	61573
TRAVMA, PLAK (TİTANYUM), FEMUR, TROCHANTERIC STABİLİZATİON,SECURELOCK	61573
TRAVMA, PLAK (TİTANYUM), PROXİMAL FEMUR, COMBIHOLE, SOL	61573
TRAVMA, PLAK (TİTANYUM), PROXİMAL FEMUR, COMBIHOLE, SAĞ	61573
TRAVMA, PLAK (TİTANYUM), FEMUR, TROCHANTERIC STABİLİZATİON, VASHOLE	61573
TRAVMA, PLAK (TİTANYUM), PROXİMAL FEMUR, SECURELOCK, SOL	61573
TRAVMA, PLAK (TİTANYUM), PROXİMAL FEMUR, SECURELOCK, SAĞ	61573
TRAVMA, PLAK (TİTANYUM), PROXİMAL FEMUR, VASHOLE, SOL	61573
TRAVMA, PLAK (TİTANYUM), PROXİMAL FEMUR, VASHOLE, SOL	61573
TRAVMA, PLAK (TİTANYUM), PROXİMAL FEMUR, VASHOLE, SAĞ	61573
TRAVMA, PLAK (TİTANYUM), FEMUR, GENİŞ DUZ, SECURELOCK	61573
TRAVMA, PLAK (TİTANYUM), FEMUR, GENİŞ DUZ, COMBIHOLE	61573
TRAVMA, PLAK (TİTANYUM), FEMUR, GENİŞ DUZ, VASHOLE	61573
TRAVMA, PLAK (TİTANYUM), FEMUR, DİSTAL, SOL, SECURELOCK	61573
TRAVMA, PLAK (TİTANYUM), FEMUR, DİSTAL, SAĞ, SECURELOCK	61573
TRAVMA, PLAK (TİTANYUM), FEMUR, DİSTAL, SOL, COMBIHOLE	61573
TRAVMA, PLAK (TİTANYUM), FEMUR, DİSTAL, SAĞ, COMBIHOLE	61573
TRAVMA, PLAK (TİTANYUM), FEMUR, DİSTAL, SAĞ, COMBIHOLE	61573
TRAVMA, PLAK (TİTANYUM), FEMUR, DİSTAL, SOL, VASHOLE	61573
TRAVMA, PLAK (TİTANYUM), FEMUR, DİSTAL, SAĞ, VASHOLE	61573
TRAVMA, PLAK (TİTANYUM), TİBİA, PROXİMAL, LATERAL, SOL, SECURELOCK	61573
TRAVMA, PLAK (TİTANYUM), TİBİA, PROXİMAL, LATERAL, SAĞ, SECURELOCK	61573
TRAVMA, PLAK (TİTANYUM), TİBİA, PROXİMAL, LATERAL, SOL, COMBIHOLE	61573
TRAVMA, PLAK (TİTANYUM), TİBİA, PROXİMAL, LATERAL, SAĞ, COMBIHOLE	61573
TRAVMA, PLAK (TİTANYUM), TİBİA, PROXİMAL, LATERAL, SAĞ, COMBIHOLE	61573
TRAVMA, PLAK (TİTANYUM), TİBİA, PROXİMAL, LATERAL, SOL, VASHOLE	61573
TRAVMA, PLAK (TİTANYUM), TİBİA, PROXİMAL, LATERAL, SAĞ, VASHOLE	61573
TRAVMA, PLAK (TİTANYUM), TİBİA, PROXİMAL, LATERAL, SAĞ, VASHOLE	61573
TRAVMA, PLAK (TİTANYUM), TİBİA, PROXİMAL, T MEDİAL, SECURELOCK	61573
TRAVMA, PLAK (TİTANYUM), TİBİA, PROXİMAL, T MEDİAL, COMBIHOLE	61573
TRAVMA, PLAK (TİTANYUM), TİBİA, PROXİMAL, T MEDİAL, VASHOLE	61573
TRAVMA, PLAK (TİTANYUM), TİBİA, PROXİMAL, T BUTTRESS, SECURELOCK	61573
TRAVMA, PLAK (TİTANYUM), TİBİA, PROXİMAL, T BUTTRESS, COMBIHOLE	61573
TRAVMA, PLAK (TİTANYUM), TİBİA, PROXİMAL, T BUTTRESS, VASHOLE	61573
TRAVMA, PLAK (TİTANYUM), TİBİA, PROXİMAL, L BUTTRESS, SOL,SECURELOCK	61573
TRAVMA, PLAK (TİTANYUM), TİBİA, PROXİMAL, L BUTTRESS, SAĞ,SECURELOCK	61573
TRAVMA, PLAK (TİTANYUM), TİBİA, PROXİMAL, L BUTTRESS, SOL,COMBIHOLE	61573
TRAVMA, PLAK (TİTANYUM), TİBİA, PROXİMAL, L BUTTRESS, SAĞ,COMBIHOLE	61573
TRAVMA, PLAK (TİTANYUM), TİBİA, PROXİMAL, L BUTTRESS, SOL,VASHOLE	61573
TRAVMA, PLAK (TİTANYUM), TİBİA, PROXİMAL, L BUTTRESS, SAĞ,VASHOLE	61573
TRAVMA, PLAK (TİTANYUM), TİBİA, DAR, DİAFİZ, SECURELOCK	61573
TRAVMA, PLAK (TİTANYUM), TİBİA, DAR, DİAFİZ, COMBIHOLE	61573
TRAVMA, PLAK (TİTANYUM), TİBİA, DAR, DİAFİZ, VASHOLE	61573
TRAVMA, PLAK (TİTANYUM), DİSTAL TİBİA/FİBULA, MEDİAL, SOL, TİBİA, SECURELOCK	61573
TRAVMA, PLAK (TİTANYUM), DİSTAL TİBİA/FİBULA, MEDİAL, SAĞ, TİBİA, SECURELOCK	61573
TRAVMA, PLAK (TİTANYUM), DİSTAL TİBİA/FİBULA, MEDİAL, SOL, TİBİA, COMBIHOLE	61573
TRAVMA, PLAK (TİTANYUM), DİSTAL TİBİA/FİBULA, MEDİAL, SOL, TİBİA, VASHOLE	61573
TRAVMA, PLAK (TİTANYUM), DİSTAL TİBİA/FİBULA, MEDİAL, SAĞ, TİBİA, VASHOLE	61573
TRAVMA, PLAK (TİTANYUM), DİSTAL TİBİA/FİBULA, LATERAL, SOL, TİBİA, SECURELOCK	61573
TRAVMA, PLAK (TİTANYUM), DİSTAL TİBİA/FİBULA, LATERAL, SAĞ, TİBİA, SECURELOCK	61573
TRAVMA, PLAK (TİTANYUM), DİSTAL TİBİA/FİBULA, LATERAL, SOL, TİBİA, COMBIHOLE	61573
TRAVMA, PLAK (TİTANYUM), DİSTAL TİBİA/FİBULA, LATERAL, SAĞ, TİBİA, COMBIHOLE	61573
TRAVMA, PLAK (TİTANYUM), DİSTAL TİBİA/FİBULA, LATERAL, SOL, TİBİA, VASHOLE	61573
TRAVMA, PLAK (TİTANYUM), DİSTAL TİBİA/FİBULA, LATERAL, SAĞ, TİBİA, VASHOLE	61573
TRAVMA, PLAK (TİTANYUM), DİSTAL TİBİA/FİBULA, FİBULA, SOL, SECURELOCK	61573
TRAVMA, PLAK (TİTANYUM), DİSTAL TİBİA/FİBULA, FİBULA, SAĞ, SECURELOCK	61573
TRAVMA, PLAK (TİTANYUM), DİSTAL TİBİA/FİBULA, FİBULA, SOL, COMBIHOLE	61573
TRAVMA, PLAK (TİTANYUM), DİSTAL TİBİA/FİBULA, FİBULA, SAĞ, COMBIHOLE	61573
TRAVMA, PLAK (TİTANYUM), DİSTAL TİBİA/FİBULA, FİBULA, SOL, VASHOLE	61573
TRAVMA, PLAK (TİTANYUM), DİSTAL TİBİA/FİBULA, FİBULA, SAĞ, VASHOLE	61573
TRAVMA, PLAK (TİTANYUM), RECONSTRUCTION, 3.5 CAP, SECURELOCK	61573
TRAVMA, PLAK (TİTANYUM), RECONSTRUCTION, 3.5 CAP, COMBIHOLE	61573
TRAVMA, PLAK (TİTANYUM), RECONSTRUCTION, 3.5 CAP, VASHOLE	61573
CYTROLOCK KİLİTLİ KALKANEUS PLAK, KOMBİNE DELİK, 64 MM, SOL	61573
CYTROLOCK KİLİTLİ KALKANEUS PLAK, KOMBİNE DELİK, 64 MM, SAĞ	61573
CYTROLOCK KİLİTLİ KALKANEUS PLAK, SECURELOCK DELİK, 64MM, SOL	61573
CYTROLOCK KİLİTLİ KALKANEUS PLAK, SECURELOCK DELİK, 64MM, SAĞ	61573
TRAVMA, PLAK (TİTANYUM), AYAK, CALCANEUS, SOL, COMBIHOLE	61573
TRAVMA, PLAK (TİTANYUM), AYAK, CALCANEUS, SAĞ, COMBIHOLE	61573
TRAVMA, PLAK (TİTANYUM), AYAK, CALCANEUS, SOL, SECURELOCK	61573
TRAVMA, PLAK (TİTANYUM), AYAK, CALCANEUS, SAĞ, SECURELOCK,	61573
TRAVMA, PLAK (TİTANYUM), AYAK, CALCANEUS, SOL, VASHOLE	61573
TRAVMA, PLAK (TİTANYUM), AYAK, CALCANEUS, SAĞ, VASHOLE	61573
TRAVMA, PLAK (TİTANYUM), AYAK, CYTROPES I HV CORRECTION PLATE, SOL, COMBIHOLE	61573
TRAVMA, PLAK (TİTANYUM), AYAK, CYTROPES I HV CORRECTION PLATE, SAĞ, COMBIHOLE	61573



UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş. 2292 Kimlik Numarası ile 93/42/EEC Tıbbi Cihazlar Yönetmeliği'nde Onaylanmış Kuruluş olarak faaliyet göstermekte olup, Bu yedi sayfalık doküman "Prosim Sağlık Anonim Şirketi" firmasına düzenlenmiş olan 27.04.2021 Tescil Tarihli M.2021.106.14494 Numaralı Belge'nin Eki'dir.

TRAVMA, PLAK (TİTANYUM), AYAK, CYTROPES II HV CORRECTION PLATE, SOL, COMBIHOLE	61573
TRAVMA, PLAK (TİTANYUM), AYAK, CYTROPES II HV CORRECTION PLATE, SAĞ, COMBIHOLE	61573
TRAVMA, PLAK (TİTANYUM), AYAK, CYTROPES I HV CORRECTION PLATE, SOL, SECURELOCK	61573
TRAVMA, PLAK (TİTANYUM), AYAK, CYTROPES I HV CORRECTION PLATE, SAĞ, SECURELOCK	61573
TRAVMA, PLAK (TİTANYUM), AYAK, CYTROPES II HV CORRECTION PLATE, SOL, SECURELOCK	61573
TRAVMA, PLAK (TİTANYUM), AYAK, CYTROPES II HV CORRECTION PLATE, SAĞ, SECURELOCK	61573
TRAVMA, PLAK (TİTANYUM), AYAK, CYTROPES I HV CORRECTION PLATE, SOL, VASHOLE	61573
CYTROLOCK KİLİTLİ KALKANEUS PLAK, DEĞİŞKEN AÇILI DELİK, 64MM, SOL, TİTANYUM	61573
TRAVMA, PLAK (TİTANYUM), AYAK, CYTROPES I HV CORRECTION PLATE, SAĞ, VASHOLE	61573
CYTROLOCK KİLİTLİ KALKANEUS PLAK, DEĞİŞKEN AÇILI DELİK, 64MM, SAĞ, TİTANYUM	61573
TRAVMA, PLAK (TİTANYUM), AYAK, CYTROPES II HV CORRECTION PLATE, SOL, VASHOLE	61573
TRAVMA, PLAK (TİTANYUM), AYAK, CYTROPES II HV CORRECTION PLATE, SAĞ, VASHOLE	61573
TRAVMA, PLAK (TİTANYUM), RECONSTRUCTION, PELVIC SECURELOCK	61573
TRAVMA, PLAK (TİTANYUM), RECONSTRUCTION, PELVIC COMBIHOLE	61573
TRAVMA, PLAK (TİTANYUM), RECONSTRUCTION, PELVIC VASHOLE	61573
TRAVMA, PLAK (TİTANYUM), HOOK PLATE, COMBIHOLE	61573
TRAVMA, PLAK (TİTANYUM), HOOK PLATE, SECURELOCK	61573
TRAVMA, PLAK (TİTANYUM), HOOK PLATE, VASHOLE	61573
TRAVMA, PLAK (TİTANYUM), WING PLATE, COMBIHOLE	61573
TRAVMA, PLAK (TİTANYUM), WING PLATE, SECURELOCK	61573
TRAVMA, PLAK (TİTANYUM), MEDIAL MALLEOLAR FIXATION SYSTEM, COMBIHOLE	61573
TRAVMA, PLAK (TİTANYUM), MEDIAL MALLEOLAR FIXATION SYSTEM WASHER	61573
TRAVMA, PLAK (TİTANYUM), MEDIAL MALLEOLAR FIXATION SYSTEM, SECURELOCK	61573
TRAVMA, PLAK (TİTANYUM), MEDIAL MALLEOLAR FIXATION SYSTEM, VASHOLE	61573
TRAVMA, PLAK (TİTANYUM), ULNA/RADIUS, KÜÇÜK LCP, DÜŞÜK PROFİL, SECURELOCK	61573
TRAVMA, PLAK (TİTANYUM), ULNA/RADIUS, KÜÇÜK LCP, DÜŞÜK PROFİL, COMBIHOLE	61573
TRAVMA, PLAK (TİTANYUM), ULNA/RADIUS, KÜÇÜK LCP, DÜŞÜK PROFİL, VASHOLE	61573
TRAVMA, PLAK (TİTANYUM), DİSTAL/RADIUS, VOLAR, 2.4 MM, SOL, KÜÇÜK, SECURELOCK	61573
TRAVMA, PLAK (TİTANYUM), DİSTAL/RADIUS, VOLAR, 2.4 MM, SAĞ, KÜÇÜK, SECURELOCK	61573
TRAVMA, PLAK (TİTANYUM), DİSTAL/RADIUS, VOLAR, 2.4 MM, SOL, ORTA, SECURELOCK	61573
TRAVMA, PLAK (TİTANYUM), DİSTAL/RADIUS, VOLAR, 2.4 MM, SAĞ, ORTA, SECURELOCK	61573
TRAVMA, PLAK (TİTANYUM), DİSTAL/RADIUS, VOLAR, 2.4 MM, SOL, BÜYÜK, SECURELOCK	61573
TRAVMA, PLAK (TİTANYUM), DİSTAL/RADIUS, VOLAR, 2.4 MM, SAĞ, BÜYÜK, SECURELOCK	61573
TRAVMA, PLAK (TİTANYUM), DİSTAL/RADIUS, VOLAR, 2.4 MM, SOL, KÜÇÜK, COMBIHOLE	61573
TRAVMA, PLAK (TİTANYUM), DİSTAL/RADIUS, VOLAR, 2.4 MM, SAĞ, KÜÇÜK, COMBIHOLE	61573
TRAVMA, PLAK (TİTANYUM), DİSTAL/RADIUS, VOLAR, 2.4 MM, SOL, ORTA, COMBIHOLE	61573
TRAVMA, PLAK (TİTANYUM), DİSTAL/RADIUS, VOLAR, 2.4 MM, SAĞ, ORTA, COMBIHOLE	61573
TRAVMA, PLAK (TİTANYUM), DİSTAL/RADIUS, VOLAR, 2.4 MM, SOL, BÜYÜK, COMBIHOLE	61573
TRAVMA, PLAK (TİTANYUM), DİSTAL/RADIUS, VOLAR, 2.4 MM, SAĞ, BÜYÜK, COMBIHOLE	61573
TRAVMA, PLAK (TİTANYUM), DİSTAL/RADIUS, VOLAR, 2.4 MM, SOL, KÜÇÜK, VASHOLE	61573
TRAVMA, PLAK (TİTANYUM), DİSTAL/RADIUS, VOLAR, 2.4 MM, SAĞ, KÜÇÜK, VASHOLE	61573
TRAVMA, PLAK (TİTANYUM), DİSTAL/RADIUS, VOLAR, 2.4 MM, SOL, ORTA, VASHOLE	61573
TRAVMA, PLAK (TİTANYUM), DİSTAL/RADIUS, VOLAR, 2.4 MM, SAĞ, ORTA, VASHOLE	61573
TRAVMA, PLAK (TİTANYUM), DİSTAL/RADIUS, VOLAR, 2.4 MM, SOL, BÜYÜK, VASHOLE	61573
TRAVMA, PLAK (TİTANYUM), DİSTAL/RADIUS, VOLAR, 2.4 MM, SAĞ, BÜYÜK, VASHOLE	61573
TRAVMA, PLAK (TİTANYUM), AYAK, H PLAK, SECURELOCK, 00	61573
TRAVMA, PLAK (TİTANYUM), AYAK, H PLAK, COMBIHOLE, 00	61573
TRAVMA, PLAK (TİTANYUM), AYAK, H PLAK, VASHOLE, 00	61573
TRAVMA, PLAK (TİTANYUM), AYAK, FUSION PLAK, SOL, SECURELOCK	61573
TRAVMA, PLAK (TİTANYUM), AYAK, FUSION PLAK, SAĞ, SECURELOCK	61573
TRAVMA, PLAK (TİTANYUM), AYAK, FUSION PLAK, SOL, COMBIHOLE	61573
TRAVMA, PLAK (TİTANYUM), AYAK, FUSION PLAK, SAĞ, COMBIHOLE	61573
TRAVMA, PLAK (TİTANYUM), AYAK, FUSION PLAK, SOL, VASHOLE	61573
TRAVMA, PLAK (TİTANYUM), AYAK, FUSION PLAK, SAĞ, VASHOLE	61573
TRAVMA, PLAK (TİTANYUM), KLAVİKULA, ANTERİOR MEDIAL, SECURELOCK	61573
TRAVMA, PLAK (TİTANYUM), KLAVİKULA, ANTERİOR MEDIAL, COMBIHOLE	61573
TRAVMA, PLAK (TİTANYUM), KLAVİKULA, ANTERİOR MEDIAL, VASHOLE	61573
TRAVMA, PLAK (TİTANYUM), KLAVİKULA, ANTERİOR LATERAL, SECURELOCK	61573
TRAVMA, PLAK (TİTANYUM), KLAVİKULA, ANTERİOR LATERAL, COMBIHOLE	61573
TRAVMA, PLAK (TİTANYUM), KLAVİKULA, ANTERİOR LATERAL, VASHOLE	61573
TRAVMA, PLAK (TİTANYUM), PROXİMAL RADIUS, SOL, SECURELOCK	61573
TRAVMA, PLAK (TİTANYUM), PROXİMAL RADIUS, SAĞ, SECURELOCK	61573
TRAVMA, PLAK (TİTANYUM), PROXİMAL RADIUS, SOL, COMBIHOLE	61573
TRAVMA, PLAK (TİTANYUM), PROXİMAL RADIUS, SAĞ, COMBIHOLE	61573
TRAVMA, PLAK (TİTANYUM), PROXİMAL RADIUS, SOL, VASHOLE	61573
TRAVMA, PLAK (TİTANYUM), PROXİMAL RADIUS, SAĞ, VASHOLE	61573
TRAVMA, PLAK (TİTANYUM), DİSTAL/ULNA, DÜZ PLAK, SECURELOCK	61573
TRAVMA, PLAK (TİTANYUM), DİSTAL/ULNA, DÜZ PLAK, COMBIHOLE	61573
TRAVMA, PLAK (TİTANYUM), DİSTAL/ULNA, DÜZ PLAK, VASHOLE	61573
TRAVMA, PLAK (TİTANYUM), BİLEK, FUSION PLAK, SECURELOCK	61573
TRAVMA, PLAK (TİTANYUM), BİLEK, FUSION PLAK, COMBIHOLE	61573
TRAVMA, PLAK (TİTANYUM), BİLEK, FUSION PLAK, VASHOLE	61573
TRAVMA, PLAK (TİTANYUM), TROCHANTERIC GRIP PLAK, COMBIHOLE	61573
TRAVMA, PLAK (TİTANYUM), TROCHANTERIC GRIP PLAK, SECURELOCK	61573
TRAVMA, PLAK (TİTANYUM), TROCHANTERIC GRIP PLAK, VASHOLE	61573
TRAVMA, PLAK (TİTANYUM) CYTROTOMY, TIBİAL OSTEOTOMİ PLAK, COMBIHOLE	61573



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TRAVMA, PLAK (TİTANYUM) CYTROLOGY, TIBİAL OSTEOTOMİ PLAK, SECURELOCK	61573
TRAVMA, PLAK (TİTANYUM) CYTROLOGY, TIBİAL OSTEOTOMİ PLAK, VASHOLE	61573
CYTROLOCK KİLİTLİ PELVİK J-REKONSTRÜKSİYON PLAK, SECURELOCK DELİK, SAĞ	61573
CYTROLOCK KİLİTLİ PELVİK J-REKONSTRÜKSİYON PLAK, SECURELOCK DELİK, SAĞ	61573
CYTROLOCK KİLİTLİ PELVİK J-REKONSTRÜKSİYON PLAK, KOMBİNE DELİK, SOL	61573
CYTROLOCK KİLİTLİ PELVİK J-REKONSTRÜKSİYON PLAK, KOMBİNE DELİK, SAĞ	61573
CYTROLOCK KİLİTLİ PELVİK J-REKONSTRÜKSİYON PLAK, DEĞİŞKEN AÇILI, SOL	61573
CYTROLOCK KİLİTLİ PELVİK J-REKONSTRÜKSİYON PLAK, DEĞİŞKEN AÇILI, SAĞ	61573
CYTROLOCK KİLİTLİ 3.5 T-OBLUK PLAK, SECURELOCK DELİK, SOL	61573
CYTROLOCK KİLİTLİ 3.5 T-OBLUK PLAK, SECURELOCK DELİK, SAĞ	61573
CYTROLOCK KİLİTLİ 3.5 T-OBLUK PLAK, KOMBİNE DELİK, SOL	61573
CYTROLOCK KİLİTLİ 3.5 T-OBLUK PLAK, KOMBİNE DELİK, SAĞ	61573
CYTROLOCK KİLİTLİ 3.5 T-OBLUK PLAK, DEĞİŞKEN AÇILI DELİK, SOL	61573
CYTROLOCK KİLİTLİ 3.5 T-OBLUK PLAK, DEĞİŞKEN AÇILI DELİK, SAĞ	61573
CYTROLOCK KİLİTLİ 3.5 T-PLAK, SECURELOCK DELİK, BÜYÜK	61573
CYTROLOCK KİLİTLİ 3.5 T-PLAK, KOMBİNE DELİK, BÜYÜK	61573
CYTROLOCK KİLİTLİ 3.5 T-PLAK, DEĞİŞKEN AÇILI DELİK, BÜYÜK	61573
CYTROLOCK KİLİTLİ 3.5 T-PLAK, SECURELOCK DELİK, KÜÇÜK	61573
CYTROLOCK KİLİTLİ 3.5 T-PLAK, SECURELOCK DELİK, KÜÇÜK	61573
CYTROLOCK KİLİTLİ 3.5 T-PLAK, KOMBİNE DELİK, KÜÇÜK	61573
CYTROLOCK KİLİTLİ 3.5 T-PLAK, DEĞİŞKEN AÇILI DELİK, KÜÇÜK	61573
TRAVMA, PLAK (TİTANYUM), TİBİA, PROXİMAL, L MEDİAL, SOL, SECURELOCK	61573
TRAVMA, PLAK (TİTANYUM), MEDİAL YÜKSEK OSTEOTOMİ PLAĞI, SECURELOCK	61573
TRAVMA, PLAK (TİTANYUM), TİBİA, PROXİMAL, L MEDİAL, SAĞ, SECURELOCK	61573
TRAVMA, PLAK (TİTANYUM), TİBİA, PROXİMAL, L MEDİAL, SOL, COMBİHOLE	61573
TRAVMA, PLAK (TİTANYUM), MEDİAL YÜKSEK OSTEOTOMİ PLAĞI, COMBİHOLE	61573
TRAVMA, PLAK (TİTANYUM), TİBİA, PROXİMAL, L MEDİAL, SAĞ, COMBİHOLE	61573
TRAVMA, PLAK (TİTANYUM), TİBİA, PROXİMAL, L MEDİAL, SOL, VASHOLE	61573
TRAVMA, PLAK (TİTANYUM), TİBİA, PROXİMAL, L MEDİAL, SAĞ, VASHOLE	61573
TRAVMA, PLAK (TİTANYUM), DİSTAL TİBİA PİLON PLAĞI, SECURELOCK	61573
TRAVMA, PLAK (TİTANYUM), DİSTAL TİBİA PİLON PLAĞI, COMBİHOLE	61573
TRAVMA, PLAK (TİTANYUM), 2.4 DORSAL, DİSTAL RADIUS PLAĞI, KAFADA 2 DELİK, SHAFT DELİK, SECURELOCK, SOL	61573
TRAVMA, PLAK (TİTANYUM), 2.4 DORSAL, DİSTAL RADIUS PLAĞI, KAFADA 2 DELİK, SHAFT DELİK, SECURELOCK, SAĞ	61573
TRAVMA, PLAK (TİTANYUM), 2.4 DORSAL, DİSTAL RADIUS PLAĞI, KAFADA 2 DELİK, SHAFT DELİK, COMBİHOLE, SOL	61573
TRAVMA, PLAK (TİTANYUM), 2.4 DORSAL, DİSTAL RADIUS PLAĞI, KAFADA 2 DELİK, SHAFT DELİK, COMBİHOLE, SAĞ	61573
TRAVMA, PLAK (TİTANYUM), 2.4 DORSAL, DİSTAL RADIUS L-PLAĞI, KAFADA 2 DELİK, SHAFT DELİK, SECURELOCK, SOL	61573
TRAVMA, PLAK (TİTANYUM), 2.4 DORSAL, DİSTAL RADIUS L-PLAĞI, KAFADA 2 DELİK, SHAFT DELİK, SECURELOCK, SAĞ	61573
TRAVMA, PLAK (TİTANYUM), 2.4 DORSAL, DİSTAL RADIUS L-PLAĞI, KAFADA 2 DELİK, SHAFT DELİK, COMBİHOLE, SOL	61573
TRAVMA, PLAK (TİTANYUM), 2.4 DORSAL, DİSTAL RADIUS L-PLAĞI, KAFADA 2 DELİK, SHAFT 5 DELİK, COMBİHOLE, SOL	61573
TRAVMA, PLAK (TİTANYUM), 2.4 DORSAL, DİSTAL RADIUS L-PLAĞI, KAFADA 2 DELİK, SHAFT 5 DELİK, COMBİHOLE, SAĞ	61573
TRAVMA, PLAK (TİTANYUM), 2.4 DORSAL, DİSTAL RADIUS L-PLAĞI, KAFADA 3 DELİK, SHAFT 3 DELİK, SECURELOCK, SOL	61573
TRAVMA, PLAK (TİTANYUM), 2.4 DORSAL, DİSTAL RADIUS L-PLAĞI, KAFADA 3 DELİK, SHAFT 5 DELİK, SECURELOCK, SOL	61573
TRAVMA, PLAK (TİTANYUM), 2.4 DORSAL, DİSTAL RADIUS L-PLAĞI, KAFADA 3 DELİK, SHAFT 3 DELİK, SECURELOCK, SAĞ	61573
TRAVMA, PLAK (TİTANYUM), 2.4 DORSAL, DİSTAL RADIUS L-PLAĞI, KAFADA 3 DELİK, SHAFT 5 DELİK, SECURELOCK, SAĞ	61573
TRAVMA, PLAK (TİTANYUM), 2.4 DORSAL, DİSTAL RADIUS L-PLAĞI, KAFADA 3 DELİK, SHAFT 3 DELİK, COMBİHOLE, SOL	61573
TRAVMA, PLAK (TİTANYUM), 2.4 DORSAL, DİSTAL RADIUS L-PLAĞI, KAFADA 3 DELİK, SHAFT 5 DELİK, COMBİHOLE, SAĞ	61573
TRAVMA, PLAK (TİTANYUM), 2.4 DORSAL, DİSTAL RADIUS L-PLAĞI, KAFADA 3 DELİK, SHAFT 5 DELİK, COMBİHOLE, SAĞ	61573
TRAVMA, PLAK (TİTANYUM), 2.4 DORSAL, DİSTAL RADIUS T-PLAĞI, SECURELOCK, KAFADA 3 DELİK, SHAFT 3 DELİK	61573
TRAVMA, PLAK (TİTANYUM), 2.4 DORSAL, DİSTAL RADIUS T-PLAĞI, COMBİHOLE, KAFADA 3 DELİK, SHAFT 3 DELİK	61573
TRAVMA, PLAK (TİTANYUM), 2.4 DORSAL, DİSTAL RADIUS T-PLAĞI, SECURELOCK, KAFADA 3 DELİK, SHAFT 5 DELİK	61573
TRAVMA, PLAK (TİTANYUM), 2.4 DORSAL, DİSTAL RADIUS T-PLAĞI, COMBİHOLE, KAFADA 3 DELİK, SHAFT 5 DELİK	61573
TRAVMA, PLAK (TİTANYUM), 1.0/1.3 LCP DÜZ MİNİ PLAK, SECURELOCK,	61573
TRAVMA, PLAK (TİTANYUM), 1.0/1.3 LCP DÜZ MİNİ PLAK, COMBİHOLE	61573
TRAVMA, PLAK (TİTANYUM), 1.0/1.3 LCP KİLİTLİ T-MİNİ PLAK, SECURELOCK	61573
TRAVMA, PLAK (TİTANYUM), 1.0/1.3 LCP KİLİTLİ T-MİNİ PLAK, COMBİHOLE	61573
TRAVMA, PLAK (TİTANYUM), 1.0/1.3 KİLİTLİ STRUT MİNİ PLAK, SECURELOCK, SOL	61573
TRAVMA, PLAK (TİTANYUM), 1.0/1.3 KİLİTLİ STRUT MİNİ PLAK, SECURELOCK, SAĞ	61573
TRAVMA, PLAK (TİTANYUM), 1.0/1.3 KİLİTLİ STRUT MİNİ PLAK, COMBİHOLE, SOL	61573
TRAVMA, PLAK (TİTANYUM), 1.0/1.3 KİLİTLİ STRUT MİNİ PLAK, COMBİHOLE, SAĞ	61573
TRAVMA, PLAK (TİTANYUM), 1.0/1.3 KİLİTLİ Y-MİNİ PLAK, SECURELOCK	61573
TRAVMA, PLAK (TİTANYUM), 1.0/1.3 KİLİTLİ Y-MİNİ PLAK, COMBİHOLE	61573
TRAVMA, PLAK (TİTANYUM), 1.0/1.3 KİLİTLİ OFSET MİNİ PLAK, SECURELOCK	61573
TRAVMA, PLAK (TİTANYUM), 1.0/1.3 KİLİTLİ OFSET MİNİ PLAK, COMBİHOLE	61573
TRAVMA, PLAK (TİTANYUM), 1.0/1.3 KİLİTLİ MEDİAL/LATERAL EĞİMLİ MİNİ PLAK, SECURELOCK	61573
TRAVMA, PLAK (TİTANYUM), 1.0/1.3 KİLİTLİ MEDİAL/LATERAL EĞİMLİ MİNİ PLAK, COMBİHOLE	61573
TRAVMA, PLAK (TİTANYUM), 1.0/1.3 KİLİTLİ KANCALI MİNİ PLAK, SECURELOCK	61573
TRAVMA, PLAK (TİTANYUM), 1.0/1.3 KİLİTLİ KANCALI MİNİ PLAK, COMBİHOLE	61573
TRAVMA, PLAK (TİTANYUM), 1.5 LCP DÜZ MİNİ PLAK, SECURELOCK	61573
TRAVMA, PLAK (TİTANYUM), 1.5 LCP DÜZ MİNİ PLAK, COMBİHOLE	61573
TRAVMA, PLAK (TİTANYUM), 1.5 LCP KİLİTLİ DÜZ MİNİ PLAK, SECURELOCK	61573
TRAVMA, PLAK (TİTANYUM), 1.5 LCP KİLİTLİ DÜZ MİNİ PLAK, COMBİHOLE	61573
TRAVMA, PLAK (TİTANYUM), 1.5 LCP KİLİTLİ T-MİNİ PLAK, SECURELOCK	61573
TRAVMA, PLAK (TİTANYUM), 1.5 LCP KİLİTLİ T-MİNİ PLAK, COMBİHOLE	61573
TRAVMA, PLAK (TİTANYUM), 1.5 KİLİTLİ STRUT MİNİ PLAK, SECURELOCK, SOL	61573





UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş. 2292 Kimlik Numarası ile 93/42/EEC Tıbbi Cihazlar Yönetmeliği'nde Onaylanmış Kuruluş olarak faaliyet göstermekte olup, Bu yedi sayfalık doküman "Prosim Sağlık Anonim Şirketi" firmasına düzenlenmiş olan 27.04.2021 Tescil Tarihli M.2021.106.14494 Numaralı Belge'nin Eki'dir.

TRAVMA, PLAK (TİTANYUM), 1.5 KİLİTLİ STRUT MİNİ PLAK, SECURELOCK, SAĞ	61573
TRAVMA, PLAK (TİTANYUM), 1.5 KİLİTLİ STRUT MİNİ PLAK, COMBİHOLE, SOL	61573
TRAVMA, PLAK (TİTANYUM), 1.5 KİLİTLİ STRUT MİNİ PLAK, COMBİHOLE, SAĞ	61573
TRAVMA, PLAK (TİTANYUM), 1.5 KİLİTLİ Y-MİNİ PLAK, SECURELOCK	61573
TRAVMA, PLAK (TİTANYUM), 1.5 KİLİTLİ Y-MİNİ PLAK, COMBİHOLE	61573
TRAVMA, PLAK (TİTANYUM), 1.5 KİLİTLİ OFSET MİNİ PLAK, SECURELOCK	61573
TRAVMA, PLAK (TİTANYUM), 1.5 KİLİTLİ OFSET MİNİ PLAK, COMBİHOLE	61573
TRAVMA, PLAK (TİTANYUM), 1.5 KİLİTLİ MEDİAL/LATERAL EĞİMLİ MİNİ PLAK, SECURELOCK	61573
TRAVMA, PLAK (TİTANYUM), 1.5 KİLİTLİ MEDİAL/LATERAL EĞİMLİ MİNİ PLAK, COMBİHOLE	61573
TRAVMA, PLAK (TİTANYUM), 2.0 LCP DÜZ MİNİ PLAK, SECURELOCK	61573
TRAVMA, PLAK (TİTANYUM), 2.0 LCP DÜZ MİNİ PLAK, COMBİHOLE	61573
TRAVMA, PLAK (TİTANYUM), 2.0 LCP KİLİTLİ DÜZ MİNİ PLAK, SECURELOCK	61573
TRAVMA, PLAK (TİTANYUM), 2.0 LCP KİLİTLİ DÜZ MİNİ PLAK, COMBİHOLE	61573
TRAVMA, PLAK (TİTANYUM), 2.0 LCP KİLİTLİ T-MİNİ PLAK, SECURELOCK	61573
TRAVMA, PLAK (TİTANYUM), 2.0 LCP KİLİTLİ T-MİNİ PLAK, COMBİHOLE	61573
TRAVMA, PLAK (TİTANYUM), 2.0 KİLİTLİ STRUT MİNİ PLAK, SECURELOCK, SOL	61573
TRAVMA, PLAK (TİTANYUM), 2.0 KİLİTLİ STRUT MİNİ PLAK, SECURELOCK, SAĞ	61573
TRAVMA, PLAK (TİTANYUM), 2.0 KİLİTLİ STRUT MİNİ PLAK, COMBİHOLE, SOL	61573
TRAVMA, PLAK (TİTANYUM), 2.0 KİLİTLİ STRUT MİNİ PLAK, COMBİHOLE, SAĞ	61573
TRAVMA, PLAK (TİTANYUM), 2.0 KİLİTLİ STRUT MİNİ PLAK, SECURELOCK, SMALL	61573
TRAVMA, PLAK (TİTANYUM), 2.0 KİLİTLİ STRUT MİNİ PLAK, COMBİHOLE, SMALL	61573
TRAVMA, PLAK (TİTANYUM), 2.0 KİLİTLİ STRUT MİNİ PLAK, COMBİHOLE, MEDIUM	61573
TRAVMA, PLAK (TİTANYUM), 2.0 KİLİTLİ STRUT MİNİ PLAK, SECURELOCK, MEDIUM	61573
TRAVMA, PLAK (TİTANYUM), 2.0 KİLİTLİ Y-MİNİ PLAK, SECURELOCK	61573
TRAVMA, PLAK (TİTANYUM), 2.0 KİLİTLİ Y-MİNİ PLAK, COMBİHOLE	61573
TRAVMA, PLAK (TİTANYUM), 2.0 KİLİTLİ CONYLAR MİNİ PLAK, SECURELOCK	61573
TRAVMA, PLAK (TİTANYUM), 2.0 KİLİTLİ CONYLAR MİNİ PLAK, COMBİHOLE	61573
TRAVMA, PLAK (TİTANYUM), 2.0 KİLİTLİ OFSET MİNİ H-PLAK, SECURELOCK,	61573
TRAVMA, PLAK (TİTANYUM), 2.0 KİLİTLİ OFSET MİNİ H-PLAK, COMBİHOLE	61573
TRAVMA, PLAK (TİTANYUM), 2.0 KİLİTLİ OFSET MİNİ PLAK, SECURELOCK/	61573
TRAVMA, PLAK (TİTANYUM), 2.0 KİLİTLİ OFSET MİNİ PLAK, COMBİHOLE/	61573
TRAVMA, PLAK (TİTANYUM), 2.0 KİLİTLİ MEDİAL/LATERAL EĞİMLİ MİNİ PLAK, SECURELOCK	61573
TRAVMA, PLAK (TİTANYUM), 2.0 KİLİTLİ MEDİAL/LATERAL EĞİMLİ MİNİ PLAK, COMBİHOLE	61573
TRAVMA, PLAK (TİTANYUM), 2.4 LCP DÜZ MİNİ PLAK, SECURELOCK	61573
TRAVMA, PLAK (TİTANYUM), 2.4 LCP DÜZ MİNİ PLAK, COMBİHOLE	61573
TRAVMA, PLAK (TİTANYUM), 2.4 LCP KİLİTLİ DÜZ MİNİ PLAK, SECURELOCK	61573
TRAVMA, PLAK (TİTANYUM), 2.4 LCP KİLİTLİ DÜZ MİNİ PLAK, COMBİHOLE	61573
TRAVMA, PLAK (TİTANYUM), 2.4 LCP KİLİTLİ T-MİNİ PLAK, SECURELOCK	61573
TRAVMA, PLAK (TİTANYUM), 2.4 LCP KİLİTLİ T-MİNİ PLAK, COMBİHOLE	61573
TRAVMA, PLAK (TİTANYUM), 2.4 LCP KİLİTLİ T-MİNİ PLAK, COMBİHOLE	61573
TRAVMA, PLAK (TİTANYUM), 2.4 KİLİTLİ STRUT MİNİ PLAK, SECURELOCK, SOL	61573
TRAVMA, PLAK (TİTANYUM), 2.4 KİLİTLİ STRUT MİNİ PLAK, SECURELOCK, SAĞ	61573
TRAVMA, PLAK (TİTANYUM), 2.4 KİLİTLİ STRUT MİNİ PLAK, COMBİHOLE, SOL	61573
TRAVMA, PLAK (TİTANYUM), 2.4 KİLİTLİ STRUT MİNİ PLAK, COMBİHOLE, SAĞ	61573
TRAVMA, PLAK (TİTANYUM), 2.4 KİLİTLİ Y-MİNİ PLAK, SECURELOCK	61573
TRAVMA, PLAK (TİTANYUM), 2.4 KİLİTLİ Y-MİNİ PLAK, COMBİHOLE	61573
TRAVMA, PLAK (TİTANYUM), 2.4 KİLİTLİ CONYLAR MİNİ PLAK, SECURELOCK, 6 DELİK, 2 DELİK KAFADA	61573
TRAVMA, PLAK (TİTANYUM), 2.4 KİLİTLİ CONYLAR MİNİ PLAK, COMBİHOLE, 6 DELİK, 2 DELİK KAFADA	61573
TRAVMA, PLAK (TİTANYUM), 2.4 KİLİTLİ CONYLAR MİNİ PLAK, SECURELOCK, SOL, PİMLİ, 6 DELİK	61573
TRAVMA, PLAK (TİTANYUM), 2.4 KİLİTLİ CONYLAR MİNİ PLAK, SECURELOCK, SAĞ, PİMLİ, 6 DELİK	61573
TRAVMA, PLAK (TİTANYUM), 2.4 KİLİTLİ CONYLAR MİNİ PLAK, COMBİHOLE, SOL, PİMLİ, 6 DELİK	61573
TRAVMA, PLAK (TİTANYUM), 2.4 KİLİTLİ CONYLAR MİNİ PLAK, COMBİHOLE, SAĞ, PİMLİ, 6 DELİK	61573
TRAVMA, PLAK (TİTANYUM), 2.4 KİLİTLİ OFSET MİNİ H-PLAK, SECURELOCK	61573
TRAVMA, PLAK (TİTANYUM), 2.4 KİLİTLİ OFSET MİNİ H-PLAK, COMBİHOLE	61573
TRAVMA, PLAK (TİTANYUM), 2.4 KİLİTLİ MEDİAL/LATERAL EĞİMLİ MİNİ PLAK, SECURELOCK	61573
TRAVMA, PLAK (TİTANYUM), 2.4 KİLİTLİ MEDİAL/LATERAL EĞİMLİ MİNİ PLAK, COMBİHOLE	61573
TRAVMA, PLAK (TİTANYUM), 1.5/2.0 DÜZELTME MİNİ PLAK, SECURELOCK,	61573
TRAVMA, PLAK (TİTANYUM), 1.5/2.0 DÜZELTME MİNİ PLAK, COMBİHOLE	61573
TRAVMA, PLAK (TİTANYUM), 2.0 DÜZELTME MİNİ PLAK, SECURELOCK	61573
TRAVMA, PLAK (TİTANYUM), 2.0 DÜZELTME MİNİ PLAK, COMBİHOLE	61573
TRAVMA, PLAK (TİTANYUM), 2.4/2.7 ÖNAYAK/ORTAAYAK L-FÜZYON KİLİTLİ PLAK, COMBİHOLE, SOL	61573
TRAVMA, PLAK (TİTANYUM), DİSTAL ULNA SAFT PLAK	61573
TRAVMA, PLAK (TİTANYUM), DORSAL BUTTRESS PLAK	61573
TRAVMA, PLAK (TİTANYUM), 2.0 ADAPTASYON PLAK, SECURELOCK	61573
TRAVMA, PLAK (TİTANYUM), 2.0 ADAPTASYON PLAK, COMBİHOLE	61573
TRAVMA, PLAK (TİTANYUM), 2.0 KİLİTLİ DÖNÜKLÜK DÜZELTME PLAK, SECURELOCK	61573
TRAVMA, PLAK (TİTANYUM), 2.0 KİLİTLİ DÖNÜKLÜK DÜZELTME PLAK, COMBİHOLE	61573
TRAVMA, PLAK (TİTANYUM), 2.0 KİLİTLİ T PLAK, SECURELOCK, 03 DELİK	61573
TRAVMA, PLAK (TİTANYUM), 2.0 KİLİTLİ T PLAK, COMBİHOLE, 03 DELİK	61573
TRAVMA, PLAK (TİTANYUM), 2.0 KİLİTLİ L-OBLİK PLAK	61573
TRAVMA, PLAK (TİTANYUM), 2.0 KİLİTLİ L PLAK	61573
TRAVMA, PLAK (TİTANYUM), 2.0 KİLİTLİ ÇİTF Y-BAŞLI PLAK,	61573
TRAVMA, PLAK (TİTANYUM), 2.0 KİLİTLİ Y-BAŞLI PLAK	61573
TRAVMA, PLAK (TİTANYUM), 3.5 KİLİTLİ Y-PLAK	61573
TRAVMA, PLAK (TİTANYUM), 2.0 MM KİLİTLİ MİNİ SUBCONDYLAR PLAK, SECURELOCK	61573
TRAVMA, PLAK (TİTANYUM), 2.0 MM KİLİTLİ MİNİ SUBCONDYLAR PLAK, COMBİHOLE	61573





UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş. 2292 Kimlik Numarası ile 93/42/EEC Tıbbi Cihazlar Yönetmeliği'nde Onaylanmış Kuruluş olarak faaliyet göstermekte olup, Bu yedi sayfalık doküman "Prosim Sağlık Anonim Şirketi" firmasına düzenlenmiş olan 27.04.2021 Tescil Tarihli M.2021.106.14494 Numaralı Belge'nin Eki'dir.

TRAVMA, PLAK (TİTANYUM), 2.0 MM KİLİTLİ MİNİ Z-PLAK, SECURELOCK	61573
TRAVMA, PLAK (TİTANYUM), 2.0 MM KİLİTLİ MİNİ Z-PLAK, COMBIHOLE	61573
TRAVMA, PLAK (TİTANYUM), Y PLAK	61573
TRAVMA, PLAK (TİTANYUM), 1.0 MİNİ ARTRODEZ DÜZ PLAK	61573
TRAVMA, PLAK (TİTANYUM), 1.0 MİNİ ARTRODEZ T PLAK	61573
TRAVMA, PLAK (TİTANYUM), 1.0 MİNİ ARTRODEZ L PLAK	61573
TRAVMA, PLAK (TİTANYUM), CYTROWEDGE PLAK	61573
TRAVMA, PLAK (TİTANYUM), EĞİMLİ FEMUR ŞAFT PLAK	61573
TRAVMA, PLAK (TİTANYUM), KABLO ATILABİLİR ATAŞMAN DÜZ PLAK	61573
TRAVMA, VİDA (TİTANYUM), KOMPRESYON, DHS/DCS	56642
TRAVMA, VİDA (TİTANYUM), KOMPRESYON, LAG VİDASI	56642
TRAVMA, VİDA (TİTANYUM), KANULLU	56642
TRAVMA, VİDA (TİTANYUM), KOMPRESYON, LAG VİDASI	56642
TRAVMA, VİDA (TİTANYUM), KANULLU, (YARIM YİV 16 MM)	56642
TRAVMA, VİDA (TİTANYUM), KANULLU, RECONSTRUCTION	56642
TRAVMA, VİDA (TİTANYUM), KANULLU, LTN KOMPRESYON,	56642
TRAVMA, VİDA (TİTANYUM), KORTİKAL,	56642
TRAVMA, VİDA (TİTANYUM), KİLİTLİ, KORTİKAL,	56642
TRAVMA, VİDA (TİTANYUM), CANCELLOUS, (TAM YİV)	56642
TRAVMA, VİDA (TİTANYUM), CANCELLOUS, (YARIM YİV)	56642
TRAVMA, VİDA (TİTANYUM), KİLİTLİ, CANCELLOUS, (TAM YİV)	56642
TRAVMA, VİDA (TİTANYUM), KİTLEME ÇİVATASI	56642
TRAVMA, VİDA (TİTANYUM), KOMPRESYON, KANULLU, HERBERT	56642
TRAVMA, VİDA (TİTANYUM), KOMPRESYON, KANULLU, KONİK	56642
TAMAMI YİVLİ KANÜLLÜ KONİK KOMPRESYON VİDASI	56642
TRAVMA, VİDA (TİTANYUM), PUL, DUSUK PROFİL	56642
6.5MM VİDALAR İÇİN PUL, KANCALI, DÜŞÜK PROFİL, TİTANYUM	56642
TRAVMA, VİDA (TİTANYUM), MALLEOLAR	56642
TRAVMA, VİDA (TİTANYUM), INSERT SPACER, 3.5 MM DELİK İÇİN	56642
TRAVMA, VİDA (TİTANYUM), KİLİTLİ, KORTİKAL, SELF DRILLING	56642
TRAVMA, VİDA (TİTANYUM), İNSERT SPACER, 5.0 MM DELİK İÇİN,	56642
TRAVMA, VİDA (TİTANYUM), KİLİTLİ, KORTİKAL, 5.0 MM SELF DRILLING	56642
TRAVMA, VİDA (TİTANYUM), DELİKLİ İNSERT, 2.0 MM KABLO İÇİN	56642
TRAVMA, VİDA (TİTANYUM), KİLİTLİ, CANCELLOUS	56642
TRAVMA, VİDA (TİTANYUM), KORTİKAL, DÜŞÜK PROFİL	56642
TRAVMA, VİDA (TİTANYUM), KİLİTLİ, CANCELLOUS, CYTROPE, LOW PROFILE	56642
TRAVMA, VİDA (TİTANYUM), KİLİTLİ, KORTİKAL, DÜŞÜK PROFİL	56642
TRAVMA, VİDA (TİTANYUM), CANCELLOUS, DÜŞÜK PROFİL	56642
TRAVMA, VİDA (TİTANYUM), KANÜLLÜ, DÜŞÜK PROFİL	56642
TRAVMA, VİDA (TİTANYUM), KOMPRESYON, KANÜLLÜ, KONİK	56642
TRAVMA, VİDA (TİTANYUM) MALLEOLAR	56642
TRAVMA, VİDA (TİTANYUM), KORTİKAL	56642
TRAVMA, VİDA (TİTANYUM), KİLİTLİ, CANCELLOUS, (TAM YİV)	56642
TRAVMA, VİDA (TİTANYUM) PROSTETİK, KİLİTLİ	56642
TRAVMA, VİDA (TİTANYUM), KİLİTLİ KANÜLLÜ KORTİKAL VİDA	56642
TRAVMA, VİDA (TİTANYUM), 7.3MM KİLİTLİ KANÜLLÜ SPONGİOS VİDA, PROKSİMAL FEMUR PLAK İÇİN	56642
TRAVMA, VİDA (TİTANYUM), KİLİTLİ, KORTİKAL	56642
TRAVMA, VİDA (TİTANYUM), ÇİFT KOMPRESYON, KANULLU	56642
TRAVMA, VİDA (TİTANYUM), KİLİTLİ, CANCELLOUS, 3.8 MM (TAM YİV)	56642
TRAVMA, VİDA (TİTANYUM), 2.7MM KİLİTLİ KORTİKAL VİDA(BAŞ 3.5MM)	56642
TRAVMA, VİDA (TİTANYUM), KİLİTLENEBİLİR PIN	56642
TRAVMA, VİDA (TİTANYUM), BAĞLANTI DÜĞME İMPLANTI	56642
CYTRONAIL TEPE VİDASI, DİNAMİK FEMORAL ÇİVİ İÇİN	56643
CYTRONAIL TEPE VİDASI, ANATOMİK FEMORAL ÇİVİ İÇİN	56643
Travma Vıda (Titanyum), Proksimal Femoral Çivi İçin, Tepe Vıdası, Kısa	56643
CYTROVIS ANTIROTASYONEL KALÇA VİDASI	56642
CYTROVIS KANÜLLÜ KALÇA VİDASI	56642
CYTROVIS FEMORAL LAG VİDA	56642
CYTROVIS KANÜLLÜ FEMORAL LAG VİDA	56642
CYTROVIS ÇİVİ FİKSASYON VİDASI, KENDİ YİV AÇAN	56642
CYTROVIS KANÜLLÜ ÇİVİ FİKSASYON VİDASI, KENDİ YİV AÇAN	56642
CYTROVIS KİLİTLİ ÇİVİ FİKSASYON VİDASI, KENDİ YİV AÇAN	56642
CYTROVIS KANÜLLÜ KİLİTLİ ÇİVİ FİKSASYON VİDA, KENDİ YİV AÇAN	56642
CYTROVIS LAG/KOMPRESYON KOMBİNE VİDA	56642
CYTROVIS LAG VİDA	56642
CYTROVIS KAYAR KALÇA VİDASI	56642
CYTROVIS ÇİFT ÇAPLI LAG VİDA	56642
CYTROVIS KİLİTLİ VİDA-PİN	56642
CYTRONAIL ÇİFT SARMAL YİVLİ VİDA	56642
CYTRONAIL OFSET TEPE VİDASI, RETROGRAD ÇİVİ İÇİN	56642
CYTRONAIL TEPE VİDASI, TİBİAL ÇİVİ İÇİN	56642
CYTROVIS ÇİVİ FİKSASYON VİDASI, TİBİAL ÇİVİ İÇİN	56642
CYTROVIS KORTİKOSPONGİOS ÇİVİ FİKSASYON VİDASI	56642
CYTROVIS ÇİVİ FİKSASYON VİDASI, KANÜLSÜZ	56642
CYTRONAIL TEPE VİDASI, DİNAMİK TİBİAL ÇİVİ İÇİN	56642
CYTROVIS ÇİVİ FİKSASYON VİDASI, KANÜLSÜZ	56642






UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş. 2292 Kimlik Numarası ile 93/42/EEC Tıbbi Cihazlar Yönetmeliği'nde Onaylanmış Kuruluş olarak faaliyet göstermekte olup, Bu yedi sayfalık doküman "Prosim Sağlık Anonim Şirketi" firmasına düzenlenmiş olan 27.04.2021 Tescil Tarihli M.2021.106.14494 Numaralı Belge'nin Eki'dir.

CYTRONAİL TEPE VİDASI	56642
CYTROVİS SPONGİOS ÇİVİ VİDASI, HUMERAL ÇİVİ İÇİN	56642
CYTROVİS ÇİVİ FİKSASYON VİDASI, HUMERAL ÇİVİ İÇİN	56642
CYTROVİS ÇİVİ FİKSASYON VİDASI, OLEKRANON ÇİVİ İÇİN	56642
CYTRONAİL DİNAMİK FEMORAL İNTRAMEDÜLER ÇİVİ	56643
CYTRONAİL ANATOMİK FEMORAL İNTRAMEDÜLER ÇİVİ, SOL	56643
CYTRONAİL ANATOMİK FEMORAL İNTRAMEDÜLER ÇİVİ, SAĞ	56643
CYTRONAİL PROKSİMAL FEMORAL ÇİVİ, KAYAR DELİKLİ	56643
Travma Çivi (Titanyum), Proksimal Femoral Çivi, Kayar Delikli, 130°	56643
CYTRONAİL PROKSİMAL FEMORAL ÇİVİ, GAMMA TİP	56643
CYTRONAİL PROKSİMAL FEMORAL ÇİVİ, KISA 125°	56643
CYTRONAİL PROKSİMAL FEMORAL ÇİVİ, KISA 130°	56643
CYTROFLEX ELASTİK ÇİVİ	61154
CYTRONAİL RETROGRAD FEMORAL ÇİVİ	56643
CYTRONAİL SUPRAKONDİLER ÇİVİ, KISA, 5 DELİKLİ	56643
CYTRONAİL SUPRAKONDİLER ÇİVİ, KISA, ÇOKLU DELİKLİ	56643
CYTRONAİL KANÜLLÜ TİBİAL İNTRAMEDÜLER ÇİVİ	56645
CYTRONAİL KANÜLSÜZ TİBİAL İNTRAMEDÜLER ÇİVİ	56645
CYTRONAİL DİNAMİK TİBİAL İNTRAMEDÜLER ÇİVİ	56645
CYTRONAİL HUMERAL İNTRAMEDÜLER ÇİVİ	56644
CYTRONAİL ÖNKOL İNTRAMEDÜLER ÇİVİ	47762
CYTRONAİL OLEKRANON OSTEOTOMİ ÇİVİSİ, PROKSİMA	47762
CYTRONAİL OLEKRANON OSTEOTOMİ ÇİVİSİ, DİSTAL	47762
CYTRONAİL DİNAMİK FEMORAL İNTRAMEDÜLER ÇİVİ, KANÜLSÜZ	56643
U STAPLE (ÇİVİ)	35615



	Uygunluk Beyannamesi (Declaration of Conformity)	Document Number	Tek.Dos.02-1.2
		Release Date	02.11.2015
		Revision Number	18
		Revision Date	15.02.2023
		Page Number	1 / 13

Uygunluk Beyannamesi (Declaration of Conformity)

Manufacturer Company Name : INVAMED SAĞLIK İLAÇ SANAYİ VE TİCARET A.Ş.
Manufacturer Company Address : Alçı OSB Mah., 2010. Cad., No:4, İç Kapı No:0, Sincan, ANKARA / TÜRKİYE
Product Name : 1- Atherectomy System
Mark : Temren
Sterile : Yes
Extra : IX
Conformity Assessment Method : Medical Device Directive 93/42/EEC Annex II (including Article 4)
Classification Rule : Rule 6 ve Rule 9
Classification : III
GMDN : 44307

Product Name : 2- Thrombectomy System
Mark : Mantis, Mantis XP, Mantis Curve
Sterile : Yes
Extra : IX
Conformity Assessment Method : Medical Device Directive 93/42/EEC Annex II (including Article 4)
Classification Rule : Rule 6, Rule 9
Classification : III
GMDN : 58172

Product Name : 3- Thrombolysis System-1
Mark : Inca
Sterile : Yes
Extra : IX
Conformity Assessment Method : Medical Device Directive 93/42/EEC Annex II (including Article 4)
Classification Rule : Rule 7
Classification : III
GMDN : 60449

Product Name : 4-Thrombolysis System-2
Mark : Viper, Invamed
Sterile : Yes
Extra : IX
Conformity Assessment Method : Medical Device Directive 93/42/EEC Annex II (including Article 4)
Classification Rule : Rule 7
Classification : III
GMDN : 32151



Uygunluk Beyannamesi (Declaration of Conformity)


Document Number	Tek.Dos.02-1.2
Release Date	02.11.2015
Revision Number	18
Revision Date	15.02.2023
Page Number	2 / 13

Product Name : 5-Thrombolysis System-3
Mark : Viper, İnvamed
Sterile : Yes
Extra : IX
Conformity Assessment Method : Medical Device Directive 93/42/EEC Annex II (including Article 4)
Classification Rule : Rule 7
Classification : III
GMDN : 59026

Product Name : 6-Thrombolysis Device
Mark : İnvamed
Sterile : Yes
Extra : IX
Conformity Assessment Method : Medical Device Directive 93/42/EEC Annex II (including Article 4)
Classification Rule : Rule 11
Classification : IIa
GMDN : 59025

Product Name : 7- Tromboaspirasyon Sistemi
Mark : Dovi, Waterjet, Angiohand
Sterile : Yes
Extra : IX
Conformity Assessment Method : Medical Device Directive 93/42/EEC Annex II (including Article 4)
Classification Rule : Rule 6
Classification : III
GMDN : 58173

Product Name : 8- Thromboaspiration Device
Mark : Dovi
Sterile : Yes
Extra : IX
Conformity Assessment Method : Medical Device Directive 93/42/EEC Annex II (Except for Article 4)
Classification Rule : Rule 11
GMDN : 41978

	Uygunluk Beyannamesi (Declaration of Conformity)	Document Number	Tek.Dos.02-1.2
		Release Date	02.11.2015
		Revision Number	18
		Revision Date	15.02.2023
		Page Number	3 / 13


Mark : 9-Keeper
Sterile : Yes
Extra : IX
Confirmity Assessment Method : Medical Device Directive 93/42/EEC Annex II (including Article 4)
Classification Rule : Rule 6
Classification : III
GMDN : 17927

Product Name : 10- Guide Catheter, Support Catheter, PTCA Microcatheter
Mark : Angiocath, Dolphin, Steercath, Ankacath, Jaguar, Invamed
Sterile : Yes
Extra : IX
Confirmity Assessment Method : Medical Device Directive 93/42/EEC Annex II (including Article 4)
Classification Rule : Rule 6
Classification : III
GMDN : 17846

Product Name : 11- Short Term Ventricular Discharge System
Mark : Invamed
Sterile : Evet
Extra : IX
Confirmity Assessment Method : Medical Device Directive 93/42/EEC Annex II (including Article 4)
Classification Rule : Rule 6
Classification : III
GMDN : 34905

Product Name : 12- Vascular Revascularization Device
Mark : King
Sterile : Yes
Extra : IX
Confirmity Assessment Method : Medical Device Directive 93/42/EEC Annex II (including Article 4)
Classification Rule : Rule 6
Classification : III
GMDN : 58173

Product Name : 13- Multibeam Catheter 1
Mark : Multibeam
Sterile : Yes
Extra : IX
Confirmity Assessment Method : Medical Device Directive 93/42/EEC Annex II (including Article 4)
Classification Rule : Rule 6
Classification : IIb

	Uygunluk Beyannamesi (Declaration of Conformity)	Document Number	Tek.Dos.02-1.2
		Release Date	02.11.2015
		Revision Number	18
		Revision Date	15.02.2023
		Page Number	4 / 13

GMDN : 61632

Product Name : 14- Multibeam Catheter 2, Multibeam Catheter 3

Mark : Multibeam

Sterile : Yes

Extra : IX

Confirmity Assessment Method : Medical Device Directive 93/42/EEC Annex II (including Article 4)

Classification Rule : Rule 6

Classification : III

GMDN : 44864

Product Name : 15- Endovenous Set

Mark : İnvamed

Sterile : Yes

Extra : IX

Confirmity Assessment Method : Medical Device Directive 93/42/EEC Annex II (including Article 4)

Classification Rule : Rule 6

Classification : III

GMDN :17846

Product Name : 16- Guide Wire

Mark : Inwire, GuideX

Sterile : Yes

Extra : IX

Confirmity Assessment Method : Medical Device Directive 93/42/EEC Annex II (including Article 4)

Classification Rule : Rule 6

Classification : III

GMDN : 35094

We declare that these products, which are under our sales and responsibility, fulfill all applicable requirements of the EU 93/42/EEC directive dated 14 July 1993 (including the 2007/47/EC revision) and the requirements of the relevant harmonized standards. All supporting documentation is kept in the facilities of INVAMED. INVAMED declares that it will fulfill the requirements of the Quality System and that it will maintain the quality system completely and effectively.

Approved Organization Name : UDEM Uluslararası Belgelendirme Denetim Eğitim Ltd. Şti.


Approved Organization Address : Mutlukent Mah. 2073 Sk. No:10 Ümitköy-Çankaya-ANKARA

Approved Organization Number : 2292


Certificate Number : M.2016.106.6913; M.2016.106.6913-1

Report Number : MD.3091.YB

Initial Certification Audit : 14.03.2016

	Uygunluk Beyannamesi (Declaration of Conformity)	Document Number	Tek.Dos.02-1.2
		Release Date	02.11.2015
		Revision Number	18
		Revision Date	15.02.2023
		Page Number	5 / 13

Certificate Registration Date : 04.08.2016
 Recertification Audit : 15.11.2019
 Recertification Date / No : 18.05.2021 / 01
 Revision Date / No : 21.05.2021 / 01
 Certificate Validity Date : 27.05.2024

AUTHORIZED	PLACE / DATE ORGANIZED	SIGNATURE/STAMP
İLKER CÖMERTOĞLU (Company Official)	15.02.2023	

1. Area of Use

Atherectomy; It is used in vessels with atherosclerotic plaque formation in the intra-body arterial peripheral and coronary vessels.

Thrombectomy Group; It is used in vessels with intra-body arterial peripheral and coronary occlusion.

Aspiration Systems; It is used in peripheral and coronary vessels, pulmonary artery, peripheral occlusions, acute arterial thrombus and acute vein thrombi.

Guide and Support Catheters; It is used as an adjunct to atherectomy, thrombectomy and aspiration systems, to provide direct external communication to a cavity in the body in coronary and peripheral intravenous applications.

2. Relevant and Applied Standards

2.1 Relevant Standards

It is detailed in the Basic Requirements within the scope of the technical file and is listed in the technical standards.

1.2. Applied Technical Standards

Document Number	Document Name	Revision Date
EN ISO 13485	Medical devices - Quality management systems - Requirements for regulatory purposes	2016/A11:2021
EN ISO 20417	Information provided by medical device manufacturers	2021



**Uygunluk Beyannamesi
(Declaration of
Conformity)**

Document Number	Tek.Dos.02-1.2
Release Date	02.11.2015
Revision Number	18
Revision Date	15.02.2023
Page Number	6 / 13

Document Number	Document Name	Revision Date
EN ISO 15223-1	Medical devices - Symbols to be used on medical device labels, labeling and information to be presented - Part 1: General requirements	2021
<i>EN ISO 14971</i>	Medical devices – Applying risk management to medical devices	<i>2019/A11:2021</i>
EN ISO 24971	Medical devices - Guidance for the implementation of ISO 14971	2020
EN ISO 11135	Sterilization of healthcare equipment - Ethylene oxide - Requirements for the development, validation and routine control of the sterilization process of medical devices	2014/A1:2019
EN ISO 11607-1	Packaging for ultimately sterilized medical devices - Part 1: Rules for materials, sterile barrier systems and packaging systems	<i>2020/A11:2022</i>
EN ISO 11607-2	Packaging of medical devices - Final sterilization - Part 2: Validation requirements for forming, sealing and joining processes	<i>2020/A11:2022</i>
EN ISO 10555-1	Intravenous catheters - Sterile, disposable - Part 1: General specifications	2013/A1:2017
EN ISO 80369-7	Small diameter connectors for liquids and gases in healthcare applications – Part 7: Connectors for intravenous or hypodermic applications	2021
EN ISO 80369-20	Small diameter binders for liquids and gases in healthcare applications - Part 20: Common test methods	2015
EN 60601-1	Electrical medical equipment - Part 1: General rules for basic safety and required performance	<i>2006/A2:2021</i>
EN 60601-1-2	Electrical medical equipment - Part 1-2: General requirements for basic safety and required performance - Supplementary standard: Electromagnetic disturbances - Specifications and tests	<i>2015/A1:2021</i>
EN 60601-1-6	Electrical medical equipment - Part 1-6: General rules for basic safety and required performance - Supplementary standard: Ease of use	2010/A2:2021



**Uygunluk Beyannamesi
(Declaration of
Conformity)**

Document Number	Tek.Dos.02-1.2
Release Date	02.11.2015
Revision Number	18
Revision Date	15.02.2023
Page Number	7 / 13

Document Number	Document Name	Revision Date
EN 556-1	Sterilization of medical devices - Specifications for medical devices to be marked "sterile" - Part 1: Specifications of medical devices that are finally sterilized	2001/AC:2006
EN ISO 11737-1	Sterilization of healthcare products - Microbiological methods - Part 1: Detection of the microorganism population on products	2018/A1:2021
EN ISO 11737-2	Sterilization of medical devices - Microbiological methods - Part 2: Sterilization tests for the validity of a sterilization process	2020
EN ISO 25539-1	<i>Cardiovascular implants - Endovascular devices - Part 1: Endovascular prostheses</i>	2017
EN ISO 25539-3	Cardiovascular implants - Endovascular devices - Part 3: Vena cava filters	2011
EN ISO 7198	<i>Cardiovascular implants and extracorporeal systems - Vascular prostheses - Tubular vascular grafts and vascular patches</i>	2017
EN 62366-1	Medical devices - Part 1: Application of usability technique to medical devices	2015/A1:2020
EN ISO 10993-1	Biological evaluation of medical devices - Part 1: Evaluation and experimentation in a risk management process - Technical Revision 1 (ISO 10993-1:2009/Correction 1:2010)	2020
EN ISO 10993-2	Biological evaluation of medical devices - Part 2: Animal health properties	2022
EN ISO 10993-3	Biological evaluation of medical devices – Part 3: Test for genotoxicity, carcinogenicity and reproductive toxicity	2014
EN ISO 10993-4	Biological evaluation of medical devices - Part 4: Selection of blood interaction experiments	2017
EN ISO 10993-5	Biological evaluation of medical devices - part 5: In vitro cytotoxicity tests	2009
EN ISO 10993-7	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residues (ISO 10993-7:2008)	2008/A1:2022
<i>ISO 10993-10</i>	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization (ISO 10993-10:2010)	2021



**Uygunluk Beyannamesi
(Declaration of
Conformity)**

Document Number	Tek.Dos.02-1.2
Release Date	02.11.2015
Revision Number	18
Revision Date	15.02.2023
Page Number	8 / 13

Document Number	Document Name	Revision Date
EN ISO 10993-11	Biological evaluation of medical devices - part 11: Systemic toxicity tests	2018
EN ISO 10993-12	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials	2021
EN ISO 10993-16	Biological evaluation of medical devices - Part 16: Toxokinetic study design for decomposition products and extractables	2017
EN ISO 10993-18	Biological evaluation of medical devices - part 18: Determination of chemical properties of materials	2020
EN ISO 14644-1	Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration	2015
EN ISO 14644-2	Cleanrooms and associated controlled environments - Part 2: Monitoring the provision of evidence of cleanroom performance of air cleaning by particle concentration	2015
EN ISO 14644-3	Clean rooms and their associated controlled environments - Part 3 - Test methods	2019
EN ISO 14644-4	Cleanrooms and associated controlled environments - Part 4: Design, construction and start-up	2003
EN ISO 14644-5	Cleanrooms and associated controlled environments - Part 5: Business	2004
EN ISO 14644-7	Cleanrooms and associated controlled environments - part 7: Separator enclosures (fresh air hoods, glove boxes, isolators and mini-environments)	2004
EN ISO 14644-8	Clean rooms and connected controlled environments - Part 8: Classification of airborne molecular contamination	2022
EN 17141	Clean rooms and related controlled environments - Biocontamination control	2020
EN ISO 11138-1	Sterilization of healthcare products - Biological indicators - Part 1: General requirements	2017
EN ISO 11138-2	Sterilization of healthcare products - Biological indicators - Part 2: Biological indicators for sterilization processes with ethylene oxide	2017



**Uygunluk Beyannamesi
(Declaration of
Conformity)**

Document Number	Tek.Dos.02-1.2
Release Date	02.11.2015
Revision Number	18
Revision Date	15.02.2023
Page Number	9 / 13

Document Number	Document Name	Revision Date
EN ISO 11138-7	Sterilization of healthcare products - Biological indicators - Part 7: Guidance for selection, use and interpretation of results	2019
EN ISO 14937	Sterilization of healthcare equipment - General requirements for the specification of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices	2009
EN ISO 11140-1	Sterilization of healthcare equipment - Chemical indicators - Part 1: General specifications	2014
EN ISO 16061	Instruments used with inactive surgical implants - General specifications	2021
EN 868-5	Packaging for ultimately sterilized medical devices - Part 5: Sealable bags and rolls of porous materials and plastic film - Requirements and test methods	2018
EN ISO/IEC 17050-1	Conformity assessment - Supplier's declaration of conformity - Part 1: General requirements	2010
EN ISO/IEC 17050-2	Conformity assessment - Supplier's declaration of conformity - Part 2: Supporting documentation	2004
MEDDEV 2.4.1 rev9	Medical Devices:Guidance Document Classification Of Medical Device	2010
MEDDEV 2.5/5 rev3	Medical Devices:Translation Procedure	1998
Meddev 2.7/1 Rev.4	Clinical Data Evaluation for Medical Devices	2016
Meddev 2.12-1 Rev.8	Vigilance System for Medical Devices	2013
Meddev 2.12/2 Rev.2	After Sales Clinical Tracking for Medical Devices	2012
MDR	Medical Device Regulation	2017
93/42/EEC	Medical Device Regulation	2011
ASTM F 1980	Standard Guide to Accelerated Aging of Sterile Barrier Systems for Medical Devices	2021
Blue Guide	The Blue Guide on the Implementation of EU product rules	2022
NBOG 2010-1	Guidance for Notified Bodies audit suppliers for medical device manufacturers	2010



**Uygunluk Beyannamesi
(Declaration of
Conformity)**

Document Number	Tek.Dos.02-1.2
Release Date	02.11.2015
Revision Number	18
Revision Date	15.02.2023
Page Number	10 / 13

Document Number	Document Name	Revision Date
NBOG BPG 2014-3	Guide to Manufacturers and Notified Bodies for Reporting Design Changes and Quality System Changes	2014
MDCG 2020-3	Guidance on significant changes in the transitional provision defined in Article 120 of MDR regarding devices covered by certificates issued pursuant to MDD or AIMDD	2020
MDCG 2020-6	Required clinical evidence for CE marked medical devices within the scope of Regulation (EU) 2017/745: Directive 93/42/EEC or 90/385/EEC - Guidance for manufacturers and notified bodies	2020
MDCG 2021-24	Guidance on classification of medical devices	2021
MDCG 2018-1 Rev.04	Guidance on basic UDI-DI and changes to UDI-DI	2021
MDCG 2019-5	Registration of legacy devices at EUDAMED	2019
MDCG 2021-8	Clinical trial application/notification documents	2021
MDCG 2021-6	Regulation (EU) 2017/745 – Questions and Answers on clinical trials	2021
MDCG 2020-10	Guidance on safety reporting in clinical trials Appendix: Clinical trial summary safety report form	2020
MDCG 2020-8	Guidance on PMCF assessment report template	2020
MDCG 2020-7	Guidance on PMCF plan template	2020
MDCG 2020-6	Guidance on sufficient clinical evidence for legacy devices	2020
MDCG 2020-5	Clinical assessment guideline – Equivalence	2020
MDCG 2019-9	Summary of safety and clinical performance	2022
MDCG 2020-1	Guidance on clinical evaluation (MDR) / Performance evaluation (IVDR) of medical device software	2020
MDCG 2019-11	Nature and classification of software - Regulation (EU) 2017/745 and (EU) Regulation (EU) 2017/746	2019
MDCG 2021-5	Standardization guide for medical devices	2021
MDCG 2021-19	Integration of UDI into an organization's quality management system	2021
MDCG 2018-6	Clarifications of UDI-related responsibilities in relation to Article 16	2018



Uygunluk Beyannamesi (Declaration of Conformity)

Document Number	Tek.Dos.02-1.2
Release Date	02.11.2015
Revision Number	18
Revision Date	15.02.2023
Page Number	11 / 13

3. Product List

3.1. Atherectomy, Thrombectomy, Thrombolysis, Aspiration, Guide Wire, Guide and Support Catheter Systems

GMDN	REFERENCE NO	PRODUCT NAME	CLASS
17519	ATA0001	Temren Atherectomy System I 5F, 90 cm	Class III
17519	ATA0002	Temren Atherectomy System II 5F, 135 cm	Class III
17519	ATA0003	Temren Atherectomy System III 6F, 90 cm	Class III
17519	ATA0004	Temren Atherectomy System IV 7F, 90cm	Class III
17519	ATA0005	Temren Atherectomy System V 7F, 135 cm	Class III
58173	ATA0006	Angiohand System I 5F	Class III
58173	ATA0007	Angiohand System II 6F	Class III
58173	ATA0008	Angiohand System III 7F	Class III
58172	ATA0009	Mantis Thrombectomy System I 7F, 90cm	Class III
58172	ATA0010	Mantis Thrombectomy System II 7F, 135 cm	Class III
58172	ATA0011	Mantis XP Thrombectomy System XD 1 7F, 110 cm	Class III
58172	ATA0012	Mantis XP Thrombectomy System XD 2 7F, 135 cm	Class III
58172	ATA0013	Mantis Curve Thrombectomy System I 7F, 90 cm	Class III
58172	ATA0014	Mantis Curve Thrombectomy System II 7F, 135 cm	Class III
58172	ATA0015	Mantis Curve Thrombectomy System OTW III 8F, 90 cm	Class III
58172	ATA0016	Mantis Curve Thrombectomy System OTW IV 8F, 135 cm	Class III
32151	ATA0017	Viper Thrombolysis System I 5F, 90cm	Class III
32151	ATA0018	Viper US Pharmacomechanical Thrombolysis System II 5F, 135cm	Class III
32151	ATA0019	Viper Pharmacomechanical Thrombolysis System III	Class III
32151	ATA0020	Viper US Pharmacomechanical Thrombolysis System IV	Class III
32151	ATA0021	Pharmacomechanical Thrombolysis System V 5F, 135 cm	Class III
32151	ATA0022	Pharmacomechanical US Thrombolysis System VI 5F, 150 cm	Class III
32151	ATA0023	Pharmacomechanical Thrombolysis System VII	Class III
32151	ATA0024	Pharmacomechanical Thrombolysis Device	Class III
60449	ATA0025	Inca Thrombolysis System I 8F, 50 cm	Class III
60449	ATA0026	Inca Thrombolysis System II 8F, 40 cm	Class III
60449	ATA0027	Inca Thrombolysis System III 8F, 30 cm	Class III
60449	ATA0028	Inca Thrombolysis System VI 9F, 50 cm	Class III
60449	ATA0029	Inca Thrombolysis System V 9F, 40 cm	Class III
60449	ATA0030	Inca Thrombolysis System VI 9F, 30 cm	Class III
60449	ATA0031	Inca Thrombolysis System VII 10F, 50 cm	Class III
60449	ATA0032	Inca Thrombolysis System VIII 10F, 40 cm	Class III
60449	ATA0033	Inca Thrombolysis System IX 10F, 30 cm	Class III
17927	ATA0034	Keeper Retriever Endovascular Snare I 4F, 120 cm	Class III
17927	ATA0035	Keeper Retriever EndovascularSnare II 6F, 120cm	Class III
17927	ATA0036	Keeper Retriever Endovascular Snare III 7F, 120 cm	Class III
58173	ATA0037	King Vascular Revascularization Device K1	Class III
58173	ATA0038	King Vascular Revascularization Device K2	Class III
58173	ATA0039	King Vascular Revascularization Device B1	Class III
58173	ATA0040	King Vascular Revascularization Device B2	Class III
61632	ATA0041	Multibeam Catheter 1	Class IIb
44864	ATA0042	Multibeam Catheter 2	Class III
44864	ATA0043	Multibeam Catheter 3	Class III
17846	ATA0044	Ankacath Guide Catheter, 4F, Braided, Hydrophilic, 90 cm	Class III
17846	ATA0045	Ankacath Guide Catheter, 5F, Braided, Hydrophilic, 90 cm	Class III



**Uygunluk Beyannamesi
(Declaration of
Conformity)**

Document Number	Tek.Dos.02-1.2
Release Date	02.11.2015
Revision Number	18
Revision Date	15.02.2023
Page Number	12 / 13

17846	ATA0046	Ankacath Guide Catheter, 5F 120 cm, Straight	Class III
17846	ATA0047	Steercath Guide Catheter, 6F, Braided, Hydrophilic, 90 cm	Class III
17846	ATA0048	Steercath Guide Catheter, 7F, Braided, Hydrophilic, 90 cm	Class III
17846	ATA0049	Steercath Guide Catheter, 8F, Braided, Hydrophilic, 90 cm	Class III
17846	ATA0050	Guide Catheter, 9F, Braided, Hydrophilic, 90 cm	Class III
17846	ATA0051	Guide Catheter, 10F, Braided, Hydrophilic, 90 cm	Class III
17846	ATA0052	Angiocath Guide Catheter, 4F, Braided, Hydrophilic, Right curved, 90 cm	Class III
17846	ATA0053	Angiocath Guide Catheter, 5F, Braided, Hydrophilic, Right curved, 90 cm	Class III
17846	ATA0054	Angiocath Guide Catheter, 6F, Braided, Hydrophilic, Right curved, 90 cm	Class III
17846	ATA0055	Angiocath Guide Catheter, 7F, Braided, Hydrophilic, Right curved, 90 cm	Class III
17846	ATA0056	Angiocath Guide Catheter, 8F, Braided, Hydrophilic, Right curved, 90 cm	Class III
17846	ATA0057	Angiocath Guide Catheter, 9F, Braided, Hydrophilic, Right curved, 90 cm	Class III
17846	ATA0058	Angiocath Guide Catheter, 10F, Braided, Hydrophilic, Right curved, 90 cm	Class III
17846	ATA0059	Angiocath Guide Catheter, 4F, Braided, Hydrophilic, Left curved, 90 cm	Class III
17846	ATA0060	Angiocath Guide Catheter, 5F, Braided, Hydrophilic, Left curved, 90 cm	Class III
17846	ATA0061	Angiocath Guide Catheter, 6F, Braided, Hydrophilic, Left curved, 90 cm	Class III
17846	ATA0062	Angiocath Guide Catheter, 7F, Braided, Hydrophilic, Left curved, 90 cm	Class III
17846	ATA0063	Angiocath Guide Catheter, 8F, Braided, Hydrophilic, Left curved, 90 cm	Class III
17846	ATA0064	Angiocath Guide Catheter, 9F, Braided, Hydrophilic, Left curved, 90 cm	Class III
17846	ATA0065	Angiocath Guide Catheter, 10F, Braided, Hydrophilic, Left curved, 90 cm	Class III
17846	ATA0066	Angiocath Guide Catheter, 5F 120 cm, Judkins Left	Class III
17846	ATA0067	Angiocath Guide Catheter, 6F 120 cm, Judkins Left	Class III
17846	ATA0068	Angiocath Guide Catheter, 7F 120 cm, Judkins Left	Class III
17846	ATA0069	Angiocath Guide Catheter, 8F 120 cm, Judkins Left	Class III
17846	ATA0070	Angiocath Guide Catheter, 5F 120 cm, Judkins Right	Class III
17846	ATA0071	Angiocath Guide Catheter, 6F 120 cm, Judkins Right	Class III
17846	ATA0072	Angiocath Guide Catheter, 7F 120 cm, Judkins Right	Class III
17846	ATA0073	Angiocath Guide Catheter, 8F 120 cm, Judkins Right	Class III
17846	ATA0074	Angiocath Guide Catheter, 6F 120 cm, Judkins Right, Straight	Class III
17846	ATA0075	Angiocath Guide Catheter, 7F 120 cm, Judkins Right, Straight	Class III
17846	ATA0076	Angiocath Guide Catheter, 8F 120 cm, Judkins Right, Straight	Class III
17846	ATA0077	Dolphin Support Catheter, 4F, 90 cm	Class III
17846	ATA0078	Dolphin Support Catheter, 5F, 90 cm	Class III
17846	ATA0079	Dolphin Support Catheter, 6F, 90 cm	Class III
17846	ATA0080	Dolphin Support Catheter, 7F, 90 cm	Class III
17846	ATA0081	Dolphin Support Catheter, 8F, 90 cm	Class III
17846	ATA0082	Dolphin Support Catheter, 9F, 90 cm	Class III
34905	ATA0083	Short Term, Ventricular Discharge System I, 2 l / min	Class III
34905	ATA0084	Short Term, Ventricular Discharge System II, 3 l / min	Class III
34905	ATA0085	Short Term, Ventricular Discharge System III, 4 l / min	Class III
34905	ATA0086	Short Term, Ventricular Discharge System IV, 5 l / min	Class III
62233	ATA0087	Endovenous Set I	Class III
62233	ATA0088	Endovenous Set II	Class III
35094	ATA0089	Inwire Guidewire, 032", Hydrophilic, Distal Thinning, 260 cm	Class III
35094	ATA0090	Inwire Guidewire, 035", Hydrophilic, Distal Thinning, 260 cm	Class III
35094	ATA0091	Inwire Guidewire, 038", Hydrophilic, Distal Thinning, 260 cm	Class III
35094	ATA0092	Inwire Guidewire, 032", Hydrophilic, Distal Thinning, 290 cm	Class III
35094	ATA0093	Inwire Guidewire, 035", Hydrophilic, Distal Thinning, 290 cm	Class III
35094	ATA0094	Inwire Guidewire, 038", Hydrophilic, Distal Thinning, 290 cm	Class III
35094	ATA0095	Inwire Guidewire, Angioplasty, 014 " 150 cm	Class III
35094	ATA0096	Inwire Guidewire, Angioplasty, 014 "260 cm	Class III
35094	ATA0097	Inwire Guidewire, Angioplasty, 018 "150 cm	Class III



**Uygunluk Beyannamesi
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Page Number	13 / 13

35094	ATA0098	Inwire Guidewire, Angioplasty, 018 "260 cm	Class III
35094	ATA0099	GuideX Guidewire, Angioplasty, 035 " 150 cm	Class III
17846	ATA0100	PTCA Micro Catheter Single Lumen 1	Class III
17846	ATA0101	PTCA Micro Catheter Single Lumen 2	Class III
17846	ATA0102	PTCA Micro Catheter Single Lumen 3	Class III
17846	ATA0103	PTCA Micro Catheter Double Lumen 1	Class III
17846	ATA0104	PTCA Micro Catheter Double Lumen 2	Class III
17846	ATA0105	PTCA Micro Catheter Double Lumen 3	Class III
17846	ATA0106	PTCA Micro Catheter with Torquer 1	Class III
17846	ATA0107	PTCA Micro Catheter with Torquer 2	Class III
17846	ATA0108	PTCA Micro Catheter with Torquer 3	Class III
17846	ATA0109	Jaguar Support Catheter 1	Class III
17846	ATA0110	Jaguar Support Catheter 2	Class III
58173	ATA0111	Dovi Aspiration System I 3.4F, 150 cm	Class III
58173	ATA0112	Dovi Aspiration System II 5F, 132cm	Class III
58173	ATA0113	Dovi Thromboaspiration System III 6F, 90cm	Class III
58173	ATA0114	Dovi Thromboaspiration System IV 6F, 100cm	Class III
58173	ATA0115	Dovi Thromboaspiration System V 6F, 110cm	Class III
58173	ATA0116	Dovi Thromboaspiration System VI 6F, 115cm	Class III
58173	ATA0117	Dovi Aspiration System VII 6F, 120cm	Class III
58173	ATA0118	Dovi Aspiration System VIII 6F, 125cm	Class III
58173	ATA0119	Dovi Aspiration System IX 6F, 132cm	Class III
58173	ATA0120	Dovi Aspiration System X 6F, 135cm	Class III
58173	ATA0121	Dovi Aspiration System XI 8F, 90cm	Class III
58173	ATA0122	Dovi Aspiration System XII 8F, 95cm	Class III
58173	ATA0123	Dovi Aspiration System XIII 8F, 100cm	Class III
58173	ATA0124	Dovi Aspiration System XIV 8F, 110cm	Class III
41978	ATA0125	Dovi Aspiration Device	Class IIa
58173	ATA0126	Waterjet Thromboaspiration / Thrombolysis Device	Class IIa
58173	ATA0127	Waterjet Thromboaspiration / Thrombolysis System	Class III