



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 : Alcı OSB Mah. 2010 Cad. Dış Kapı No:4 İç Kapı No:0 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 : 10.05.2021/01
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



Address: Mutlukent Mahallesi 2073 Sokak (Eski 93 Sokak) No:10 Çankaya – Ankara – TURKEY
Phone: +90 0312 443 03 90 **Fax:** +90 0312 443 03 76
E-mail: info@udemltd.com.tr www.udem.com.tr

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



This document containing 8 (eight) pages is the Annex of the Certificate with the revision number 01, with the number M.2017.106.8756 and with the registration date of 09.08.2017 and with the re-issue date 10.05.2021 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.

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





This document containing 8 (eight) pages is the Annex of the Certificate with the revision number 01, with the number M.2017.106.8756 and with the registration date of 09.08.2017 and with the re-issue date 10.05.2021 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.

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



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

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



This document containing 8 (eight) pages is the Annex of the Certificate with the revision number 01, with the number M.2017.106.8756 and with the registration date of 09.08.2017 and with the re-issue date 10.05.2021 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.

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 revision number 01, with the number M.2017.106.8756 and with the registration date of 09.08.2017 and with the re-issue date 10.05.2021 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



This document containing 8 (eight) pages is the Annex of the Certificate with the revision number 01, with the number M.2017.106.8756 and with the registration date of 09.08.2017 and with the re-issue date 10.05.2021 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.

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