	DECLARATION OF CONFORMITY EXTENDER DRUG-RELEASED PTA BALOON	Doküman No	Tek.Dos.03-1.2
		İlk Yayım Tarihi	05/11/2015
		Revizyon No	06/22.12.2020
		Revizyon Tarihi	...\..\..\.
		Sayfa No	Sayfa 1 / 18



Declaration of Conformity

Manufacturer Company Name: Invamed Sağlık İlaç Sanayi ve Ticaret A.Ş.

Manufacturer Company Address: Anadolu OSB 30 Agustus caddesi No:13 Malıköy Ankara / Türkiye

Name of the product EXTENDER Drug-Released PTA Baloon – Class III

Brand: EXTENDER


Annex: II


Classification Rule: Rule 6, Rule 13

Classification: III

GMDN: 62551

Conformity Assessment Method: Medical Device Directive 93/42 EEC ANNEX-2 (including article 4)

AUTHORIZED PERSON	DATE OF EDIT	SIGNATURE / STAMP
İLKER CÖMERTOĞLU	22.12.2020	

	DECLARATION OF CONFORMITY EXTENDER DRUG-RELEASED PTA BALOON	Doküman No	Tek.Dos.03-1.2
		İlk Yayım Tarihi	05/11/2015
		Revizyon No	06/22.12.2020
		Revizyon Tarihi	...\.....\.....
		Sayfa No	Sayfa 2 / 18

Notified body name: UDEM Uluslararası Belgelendirme Denetim Eğitim Ltd.
Şti.
Notified body number: 2292
Certificate number: M.2017.106.8756-1
M.2017.106.8756
Certificate registration date: 09.08.2017
Certificate validity date: 27.05.2024

1. **USAGE AREA**

Peripheral Veins


2. **Relevant and Applicable Standards**

2.1. **Relevant Standards**

TD.03 Extender Drug Release PTA Balloon Catheter technical file is given in Chapter 11 Basic requirements file.


2.2. **Standards Applied**

TD.03 Extender Drug Release PTA Balloon Catheter technical file is given in Section 6 Standards List. It is additionally attached at the end of the declaration.


	DECLARATION OF CONFORMITY EXTENDER DRUG-RELEASED PTA BALOON	Doküman No	Tek.Dos.03-1.2
		İlk Yayın Tarihi	05/11/2015
		Revizyon No	06/22.12.2020
		Revizyon Tarihi	... \..... \.....
		Sayfa No	Sayfa 3 / 18

3. PRODUCT LIST


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

	DECLARATION OF CONFORMITY EXTENDER DRUG-RELEASED PTA BALOON	Doküman No	Tek.Dos.03-1.2
		İlk Yayım Tarihi	05/11/2015
		Revizyon No	06/22.12.2020
		Revizyon Tarihi	...\.....\.....
		Sayfa No	Sayfa 4 / 18


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
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

	DECLARATION OF CONFORMITY EXTENDER DRUG-RELEASED PTA BALOON	Doküman No	Tek.Dos.03-1.2
		İlk Yayım Tarihi	05/11/2015
		Revizyon No	06/22.12.2020
		Revizyon Tarihi	...\.....\.....
		Sayfa No	Sayfa 5 / 18

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
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


	DECLARATION OF CONFORMITY EXTENDER DRUG-RELEASED PTA BALOON	Doküman No	Tek.Dos.03-1.2
		İlk Yayım Tarihi	05/11/2015
		Revizyon No	06/22.12.2020
		Revizyon Tarihi	...\.....\.....
		Sayfa No	Sayfa 6 / 18

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

	DECLARATION OF CONFORMITY EXTENDER DRUG-RELEASED PTA BALLOON	Doküman No	Tek.Dos.03-1.2
		İlk Yayım Tarihi	05/11/2015
		Revizyon No	06/22.12.2020
		Revizyon Tarihi	...\.....\.....
		Sayfa No	Sayfa 7 / 18


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				

	DECLARATION OF CONFORMITY EXTENDER DRUG-RELEASED PTA BALOON	Doküman No	Tek.Dos.03-1.2
		İlk Yayım Tarihi	05/11/2015
		Revizyon No	06/22.12.2020
		Revizyon Tarihi	...\.....\.....
		Sayfa No	Sayfa 8 / 18


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
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

	DECLARATION OF CONFORMITY EXTENDER DRUG-RELEASED PTA BALOON	Doküman No	Tek.Dos.03-1.2
		İlk Yayım Tarihi	05/11/2015
		Revizyon No	06/22.12.2020
		Revizyon Tarihi	... \..... \.....
		Sayfa No	Sayfa 9 / 18


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
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

	DECLARATION OF CONFORMITY EXTENDER DRUG-RELEASED PTA BALOON	Doküman No	Tek.Dos.03-1.2
		İlk Yayım Tarihi	05/11/2015
		Revizyon No	06/22.12.2020
		Revizyon Tarihi	... \..... \.....
		Sayfa No	Sayfa 10 / 18


TER580L	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)				0.014 "Guidewire RX Drug-Released Balloons (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


	DECLARATION OF CONFORMITY EXTENDER DRUG-RELEASED PTA BALOON	Doküman No	Tek.Dos.03-1.2
		İlk Yayın Tarihi	05/11/2015
		Revizyon No	06/22.12.2020
		Revizyon Tarihi	...\.....\.....
		Sayfa No	Sayfa 11 / 18

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


NO	DOCUMENT NAME	RELEASE DATE	PLACE OF PURCHASE
1.	ASTM F 1980 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices	2002	-
2.	TS EN ISO 10993-1 Biological evaluation of medical devices - Part 1: Evaluation and testing in a risk management process (ISO 10993-1: 2009)	2011	TSE
3.	TS EN ISO 10993-2 Biological evaluation of medical devices - Part 2: Animal health characteristics	2006	TSE
4.	TS EN ISO 10993-3 Biological evaluation of medical devices - Part 3: Test for genotoxicity, carcinogenicity and reproductive toxicity	2015	TSE
5.	TS EN ISO 10993-4	2017	TSE

	DECLARATION OF CONFORMITY EXTENDER DRUG-RELEASED PTA BALOON	Doküman No	Tek.Dos.03-1.2
		İlk Yayım Tarihi	05/11/2015
		Revizyon No	06/22.12.2020
		Revizyon Tarihi	...\.....\.....
		Sayfa No	Sayfa 12 / 18


	Biological evaluation of medical devices - Part 4: Selection of blood interaction experiments		
6.	TS EN ISO 10993-5 Biological evaluation of medical devices - Part 5: In vitro cytotoxicity tests	2010	TSE
7.	TS EN ISO 10993-7 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residues (ISO 10993-7: 2008)	2010	TSE
8.	TS EN ISO 10993-7 / AC Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residues - Technical correction 1 (ISO 10993-7: 2008 / Revision 1: 2009)	2010	TSE
9.	TS EN ISO 10993-10 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitivity (ISO 10993-10: 2010)	2014	TSE
10.	TS EN ISO 10993-11 Biological evaluation of medical devices - part 11: Systemic toxicity tests	2018	TSE
11.	TS EN ISO 10993-12 Biological evaluation of medical devices - Part 12: Sample preparation and reference materials (ISO 10993-12: 2012)	2013	TSE

	DECLARATION OF CONFORMITY EXTENDER DRUG-RELEASED PTA BALOON	Doküman No	Tek.Dos.03-1.2
		İlk Yayım Tarihi	05/11/2015
		Revizyon No	06/22.12.2020
		Revizyon Tarihi	...\.....\.....
		Sayfa No	Sayfa 13 / 18


12.	TS EN ISO 14644-1 Clean rooms and their associated controlled environments - Part 1: Classification of air cleanliness by particle concentration	2016	TSE
13.	TS EN ISO 14644-2 Clean rooms and their associated controlled environments - Part 2: Documentation monitoring of clean room performance regarding particle concentration and air purification	2016	TSE
14.	TS EN ISO 14644-3 Clean rooms and their controlled environments-Part 3- Test methods	2006	TSE
15.	TS EN ISO 14644-4 Clean rooms and their associated controlled environments - Part 4: Design, construction and start-up	2006	TSE
16.	TS EN ISO 14644-5 Clean rooms and their associated controlled environments - Part 5: Operation	2006	TSE
17.	TS EN ISO 14644-7 Clean rooms and their associated controlled environments - Part 7: Separating devices (fresh air	2008	TSE

	DECLARATION OF CONFORMITY EXTENDER DRUG-RELEASED PTA BALOON	Doküman No	Tek.Dos.03-1.2
		İlk Yayın Tarihi	05/11/2015
		Revizyon No	06/22.12.2020
		Revizyon Tarihi	...\.....\.....
		Sayfa No	Sayfa 14 / 18


	hoods, glove boxes, insulators and mini-environments)		
18.	TS EN ISO 14644-8 Clean rooms and connected controlled environments - Part 8: Classification of airborne molecular contamination	2013	TSE
19.	TS EN ISO 11607-1 Packaging of medical devices - Lastly sterilized - part 1: Specifications for materials, sterile barrier systems and packaging systems	2017	TSE
20.	TS EN ISO 11607-2 Packaging of medical devices - Finally sterilized - part 2: Validation requirements for forming, sealing and joining processes	2017	TSE
21.	EN ISO 80369-7 Small diameter fasteners for liquids and gases in healthcare applications - Part 7: Fasteners for intravenous or hypodermic applications	2017	TSE
22.	TS EN ISO 10555-1 Intravenous catheters - Intravenous catheters - Sterile, single use - part 1: General characteristics	2013	TSE
23.	TS EN ISO 10555-4 Intravenous catheters-Sterile, disposable-Part 4: Balloon expansion catheters	2013	TSE

	DECLARATION OF CONFORMITY EXTENDER DRUG-RELEASED PTA BALOON	Doküman No	Tek.Dos.03-1.2
		İlk Yayın Tarihi	05/11/2015
		Revizyon No	06/22.12.2020
		Revizyon Tarihi	...\.....\.....
		Sayfa No	Sayfa 15 / 18


24.	TS EN 1041 + A1 Information provided by medical device manufacturers	2014	TSE
25.	TS EN ISO 13485 Medical devices - Quality management systems - Requirements for regulatory purposes	2016	TSE
26.	TS EN ISO 14698-1 Clean rooms and jointly controlled environments - Biocontamination control - Part 1: General principles and methods	2004	TSE
27.	TS EN ISO 14698-2 Clean rooms and co-controlled environments - Biocontamination control - Part 2: Evaluation and interpretation of biocontamination data	2004	TSE
28.	TS EN ISO 14937 Sterilization of healthcare supplies - General requirements for the determination of the properties of a sterilizing agent and for the development, validation and routine control of a sterilization process for medical devices	2011	TSE
29.	TS EN ISO 11138-2 Sterilization of health products - Biological indicators - Part 2: Biological indicators for	2017	TSE

	DECLARATION OF CONFORMITY EXTENDER DRUG-RELEASED PTA BALOON	Doküman No	Tek.Dos.03-1.2
		İlk Yayım Tarihi	05/11/2015
		Revizyon No	06/22.12.2020
		Revizyon Tarihi	...\.....\.....
		Sayfa No	Sayfa 16 / 18

	ethylene oxide sterilization processes		
30.	93/42 / EEC Medical Device Directive	2011	Sağlık Bakanlığı
31.	TS EN ISO / IEC 17050-1 Conformity assessment - Declaration of conformity of the supplier - Part 1: General requirements	2010	TSE
32.	TS EN ISO / IEC 17050-2 Conformity assessment - Declaration of conformity of the supplier - Part 2: Supporting documentation	2007	TSE
33.	TS EN ISO 15223-1 Medical devices - Symbols to be used in medical device labels, labeling and information to be presented - Part 1: General requirements	2016	TSE
34.	TS EN 556-1 Sterilization of medical devices - Specifications for medical devices to be marked as "sterile" - Part 1: Characteristics of medical devices that are finally sterilized	2009	TSE
35.	TS EN ISO 11737-1 Sterilization of medical devices - Microbiological methods - Part 1: Determination of the	2018	TSE

	DECLARATION OF CONFORMITY EXTENDER DRUG-RELEASED PTA BALOON	Doküman No	Tek.Dos.03-1.2
		İlk Yayım Tarihi	05/11/2015
		Revizyon No	06/22.12.2020
		Revizyon Tarihi	...\.....\.....
		Sayfa No	Sayfa 17 / 18

	microorganism population on the product (ISO 11737-1: 2006)		
36.	TS EN ISO 11737-1 Sterilization of health care products - Microbiological methods - Part 1: Detection of microorganism population on products	2018	TSE
37.	TS EN 62366-1 Medical devices - Part 1: Application of usability technique to medical devices	2015	TSE
38.	TS EN 62366-1 / AC-2016 Medical devices - Part 1: Application of usability technique to medical devices	2018	TSE
39.	TS EN ISO 14155 Clinical research of medical devices for humans - Good clinical practice (ISO 14155: 2011)	2016	TSE
40.	TS EN 11135 Sterilization of health supplies - Ethylene oxide - Requirements for the development, validation and routine control of the sterilization process of medical devices	2014	TSE
41.	TS EN ISO 14971 Medical devices - Application of risk management to medical devices (ISO 14971: 2007; Revised edition 2007-10-01)	2013	TSE
42.		2016	https://ec.europa.eu/docsroom

	DECLARATION OF CONFORMITY EXTENDER DRUG-RELEASED PTA BALOON	Doküman No	Tek.Dos.03-1.2
		İlk Yayım Tarihi	05/11/2015
		Revizyon No	06/22.12.2020
		Revizyon Tarihi	...\.....\.....
		Sayfa No	Sayfa 18 / 18

	Blue Guide		
43.	MEDDEV 2.12.2 Medical Devices:Guidance Document Post Market Clinical Follow Up	2012	https://ec.europa.eu/docsroom
44.	MEDDEV 2.4.1 Medical Devices:Guidance Document Classification Of Medical Device	2010	https://ec.europa.eu/docsroom
45.	MEDDEV 2.5/5 Medical Devices:Translation Procedure	1998	https://ec.europa.eu/docsroom
46.	MEDDEV 2.7.1 Rev: 4 Clinical Data Evaluation for Medical Devices	2016	https://ec.europa.eu/docsroom
47.	MEDDEV 2.12.1 Adverse incident report	2015	https://ec.europa.eu/docsroom
48.	<i>MDR Medical Device Regulation</i>	<i>May 2017</i>	https://eur-lex.europa.eu
49.	<i>TS EN ISO 12417-1 Cardiovascular implants and extracorporeal systems - Vascular device-drug combination products - Part 1: General characteristics</i>	2015	TSE
50.	EN ISO 14630 Inactive surgical implants - General features	2012	TSE