



ANNEX 1 TO THE CERTIFICATE

VALID ONLY WITH CERTIFICATE

No 1434-MDD-220/2020

List of medical devices covered by the certificate:

Sirolimus Coated PTA Balloon Catheter (0.014" OTW)

Brand name: Magic Touch PTA

Balloon Diameter (mm)	Catheter Length (Shaft Length): 120 cm/1200 mm							
	Balloon Length (mm)							
	20	40	60	80	100	120	150	200
1.50	CPT14150020							
2.00		CPT14200040	CPT14200060	CPT14200080	CPT14200100	CPT14200120	CPT14200150	CPT14200200
2.50		CPT14250040	CPT14250060	CPT14250080	CPT14250100	CPT14250120	CPT14250150	CPT14250200
3.00		CPT14300040	CPT14300060	CPT14300080	CPT14300100	CPT14300120	CPT14300150	CPT14300200
3.50		CPT14350040	CPT14350060	CPT14350080	CPT14350100	CPT14350120	CPT14350150	CPT14350200
4.00		CPT14400040	CPT14400060	CPT14400080	CPT14400100	CPT14400120	CPT14400150	CPT14400200

Balloon Diameter (mm)	Catheter Length (Shaft Length): 90 cm/900 mm							
	Balloon Length (mm)							
	20	40	60	80	100	120	150	200
1.50	CPTW14025							
2.00		CPTW14026	CPTW14027	CPTW14028	CPTW14029	CPTW14030	CPTW14031	CPTW14032
2.50		CPTW14033	CPTW14034	CPTW14035	CPTW14036	CPTW14037	CPTW14038	CPTW14039
3.00		CPTW14040	CPTW14041	CPTW14042	CPTW14043	CPTW14044	CPTW14045	CPTW14046
3.50		CPTW14047	CPTW14048	CPTW14049	CPTW14050	CPTW14051	CPTW14052	CPTW14053
4.00		CPTW14054	CPTW14055	CPTW14056	CPTW14057	CPTW14058	CPTW14059	CPTW14060

Balloon Diameter (mm)	Catheter Length (Shaft Length): 150 cm/1500 mm							
	Balloon Length (mm)							
	20	40	60	80	100	120	150	200
1.50	CPTW14061							
2.00		CPTW14062	CPTW14063	CPTW14064	CPTW14065	CPTW14066	CPTW14067	CPTW14068
2.50		CPTW14069	CPTW14070	CPTW14071	CPTW14072	CPTW14073	CPTW14074	CPTW14075
3.00		CPTW14076	CPTW14077	CPTW14078	CPTW14079	CPTW14080	CPTW14081	CPTW14082
3.50		CPTW14083	CPTW14084	CPTW14085	CPTW14086	CPTW14087	CPTW14088	CPTW14089
4.00		CPTW14090	CPTW14091	CPTW14092	CPTW14093	CPTW14094	CPTW14095	CPTW14096



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Balloon Diameter (mm)	Catheter Length (Shaft Length): 80 cm/800 mm			Catheter Length (Shaft Length): 145 cm/1450 mm		
	Balloon Length (mm)			Balloon Length (mm)		
	60	80	100	60	80	100
2.00	CPTW14013	CPTW14014	CPTW14015	CPTW14001	CPTW14002	CPTW14003
2.50	CPTW14016	CPTW14017	CPTW14018	CPTW14004	CPTW14005	CPTW14006
3.00	CPTW14019	CPTW14020	CPTW14021	CPTW14007	CPTW14008	CPTW14009
3.50	CPTW14022	CPTW14023	CPTW14024	CPTW14010	CPTW14011	CPTW14012

Sirolimus Coated PTA Balloon Catheter (0.018" OTW)

Brand name: Magic Touch PTA

Balloon Diameter (mm)	Catheter Length (Shaft Length): 120 cm/1200 mm						
	Balloon Length (mm)						
	40	60	80	100	120	150	200
2.00	CPT18200040	CPT18200060	CPT18200080	CPT18200100	CPT18200120	CPT18200150	CPT18200200
2.50	CPT18250040	CPT18250060	CPT18250080	CPT18250100	CPT18250120	CPT18250150	CPT18250200
3.00	CPT18300040	CPT18300060	CPT18300080	CPT18300100	CPT18300120	CPT18300150	CPT18300200
3.50	CPT18350040	CPT18350060	CPT18350080	CPT18350100	CPT18350120	CPT18350150	CPT18350200
4.00	CPT18400040	CPT18400060	CPT18400080	CPT18400100	CPT18400120	CPT18400150	CPT18400200
5.00	CPT18500040	CPT18500060	CPT18500080	CPT18500100	CPT18500120	CPT18500150	CPT18500200
5.50	CPT18550040	CPT18550060	CPT18550080	CPT18550100	CPT18550120	CPT18550150	CPT18550200
6.00	CPT18600040	CPT18600060	CPT18600080	CPT18600100	CPT18600120	CPT18600150	CPT18600200
7.00	CPT18700040						

Balloon Diameter (mm)	Catheter Length (Shaft Length): 90 cm/900 mm						
	Balloon Length (mm)						
	40	60	80	100	120	150	200
2.00	CPTW18099	CPTW18100	CPTW18101	CPTW18102	CPTW18103	CPTW18104	CPTW18105
2.50	CPTW18106	CPTW18107	CPTW18108	CPTW18109	CPTW18110	CPTW18111	CPTW18112
3.00	CPTW18113	CPTW18114	CPTW18115	CPTW18116	CPTW18117	CPTW18118	CPTW18119
3.50	CPTW18120	CPTW18121	CPTW18122	CPTW18123	CPTW18124	CPTW18125	CPTW18126
4.00	CPTW18127	CPTW18128	CPTW18129	CPTW18130	CPTW18131	CPTW18132	CPTW18133
5.00	CPTW18134	CPTW18135	CPTW18136	CPTW18137	CPTW18138	CPTW18139	CPTW18140
5.50	CPTW18141	CPTW18142	CPTW18143	CPTW18144	CPTW18145	CPTW18146	CPTW18147
6.00	CPTW18148	CPTW18149	CPTW18150	CPTW18151	CPTW18152	CPTW18153	CPTW18154
7.00	CPTW18155						



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Balloon Diameter (mm)	Catheter Length (Shaft Length): 150 cm/1500 mm						
	Balloon Length (mm)						
	40	60	80	100	120	150	200
2.00	CPTW18156	CPTW18157	CPTW18158	CPTW18159	CPTW18160	CPTW18161	CPTW18162
2.50	CPTW18163	CPTW18164	CPTW18165	CPTW18166	CPTW18167	CPTW18168	CPTW18169
3.00	CPTW18170	CPTW18171	CPTW18172	CPTW18173	CPTW18174	CPTW18175	CPTW18176
3.50	CPTW18177	CPTW18178	CPTW18179	CPTW18180	CPTW18181	CPTW18182	CPTW18183
4.00	CPTW18184	CPTW18185	CPTW18186	CPTW18187	CPTW18188	CPTW18189	CPTW18190
5.00	CPTW18191	CPTW18192	CPTW18193	CPTW18194	CPTW18195	CPTW18196	CPTW18197
5.50	CPTW18198	CPTW18199	CPTW18200	CPTW18201	CPTW18202	CPTW18203	CPTW18204
6.00	CPTW18205	CPTW18206	CPTW18207	CPTW18208	CPTW18209	CPTW18210	CPTW18211
7.00	CPTW18212						

Balloon Diameter (mm)	Catheter Length (Shaft Length): 80 cm/800 mm						
	Balloon Length (mm)						
	40	60	80	100	120	150	200
2.00	CPTW18050	CPTW18051	CPTW18052	CPTW18053	CPTW18054	CPTW18055	CPTW18056
2.50	CPTW18057	CPTW18058	CPTW18059	CPTW18060	CPTW18061	CPTW18062	CPTW18063
3.00	CPTW18064	CPTW18065	CPTW18066	CPTW18067	CPTW18068	CPTW18069	CPTW18070
3.50	CPTW18071	CPTW18072	CPTW18073	CPTW18074	CPTW18075	CPTW18076	CPTW18077
4.00	CPTW18078	CPTW18079	CPTW18080	CPTW18081	CPTW18082	CPTW18083	CPTW18084
5.00	CPTW18085	CPTW18086	CPTW18087	CPTW18088	CPTW18089	CPTW18090	CPTW18091
6.00	CPTW18092	CPTW18093	CPTW18094	CPTW18095	CPTW18096	CPTW18097	CPTW18098

Balloon Diameter (mm)	Catheter Length (Shaft Length): 145 cm/1450 mm						
	Balloon Length (mm)						
	40	60	80	100	120	150	200
2.00	CPTW18001	CPTW18002	CPTW18003	CPTW18004	CPTW18005	CPTW18006	CPTW18007
2.50	CPTW18008	CPTW18009	CPTW18010	CPTW18011	CPTW18012	CPTW18013	CPTW18014
3.00	CPTW18015	CPTW18016	CPTW18017	CPTW18018	CPTW18019	CPTW18020	CPTW18021
3.50	CPTW18022	CPTW18023	CPTW18024	CPTW18025	CPTW18026	CPTW18027	CPTW18028
4.00	CPTW18029	CPTW18030	CPTW18031	CPTW18032	CPTW18033	CPTW18034	CPTW18035
5.00	CPTW18036	CPTW18037	CPTW18038	CPTW18039	CPTW18040	CPTW18041	CPTW18042
6.00	CPTW18043	CPTW18044	CPTW18045	CPTW18046	CPTW18047	CPTW18048	CPTW18049



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Sirolimus Coated PTA Balloon Catheter (0.035" OTW)

Brand name: Magic Touch PTA

Balloon Diameter (mm)	Catheter Length (Shaft Length): 80 cm/800 mm							
	Balloon Length (mm)							
	20	40	60	80	100	120	150	200
3.00	CPTW35001	CPTW35002	CPTW35003	CPTW35004				
4.00	CPTW35005	CPTW35006	CPTW35007	CPTW35008	CPTW35009	CPTW35010	CPTW35011	CPTW35012
5.00	CPTW35013	CPTW35014	CPTW35015	CPTW35016	CPTW35017	CPTW35018	CPTW35019	CPTW35020
6.00	CPTW35021	CPTW35022	CPTW35023	CPTW35024	CPTW35025	CPTW35026	CPTW35027	CPTW35028
7.00	CPTW35029	CPTW35030	CPTW35031	CPTW35032	CPTW35033	CPTW35034	CPTW35035	CPTW35036
8.00	CPTW35037	CPTW35038	CPTW35039	CPTW35040	CPTW35041	CPTW35042	CPTW35043	CPTW35044
9.00	CPTW35045	CPTW35046	CPTW35047	CPTW35048				
10.00	CPTW35049	CPTW35050	CPTW35051	CPTW35052				
12.00	CPTW35053	CPTW35054	CPTW35055	CPTW35056				

Balloon Diameter (mm)	Catheter Length (Shaft Length): 90 cm/900 mm							
	Balloon Length (mm)							
	20	40	60	80	100	120	150	200
3.00	CPTW35057	CPTW35058	CPTW35059	CPTW35060				
4.00	CPTW35061	CPTW35062	CPTW35063	CPTW35064	CPTW35065	CPTW35066	CPTW35067	CPTW35068
5.00	CPTW35069	CPTW35070	CPTW35071	CPTW35072	CPTW35073	CPTW35074	CPTW35075	CPTW35076
6.00	CPTW35077	CPTW35078	CPTW35079	CPTW35080	CPTW35081	CPTW35082	CPTW35083	CPTW35084
7.00	CPTW35085	CPTW35086	CPTW35087	CPTW35088	CPTW35089	CPTW35090	CPTW35091	CPTW35092
8.00	CPTW35093	CPTW35094	CPTW35095	CPTW35096	CPTW35097	CPTW35098	CPTW35099	CPTW35100
9.00	CPTW35101	CPTW35102	CPTW35103	CPTW35104				
10.00	CPTW35105	CPTW35106	CPTW35107	CPTW35108				
12.00	CPTW35109	CPTW35110	CPTW35111	CPTW35112				

Balloon Diameter (mm)	Catheter Length (Shaft Length): 45 cm/450 mm					
	Balloon Length (mm)					
	20	40	60	80	100	120
3.00	CPTW35113	CPTW35114	CPTW35115	CPTW35116		
4.00	CPTW35117	CPTW35118	CPTW35119	CPTW35120	CPTW35121	CPTW35122
5.00	CPTW35123	CPTW35124	CPTW35125	CPTW35126	CPTW35127	CPTW35128
6.00	CPTW35129	CPTW35130	CPTW35131	CPTW35132	CPTW35133	CPTW35134
7.00	CPTW35135	CPTW35136	CPTW35137	CPTW35138	CPTW35139	
8.00	CPTW35140	CPTW35141	CPTW35142	CPTW35143	CPTW35144	
9.00	CPTW35145	CPTW35146	CPTW35147	CPTW35148		
10.00	CPTW35149	CPTW35150	CPTW35151	CPTW35152		



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Balloon Diameter (mm)	Catheter Length (Shaft Length): 130 cm/1300 mm							
	Balloon Length (mm)							
	20	40	60	80	100	120	150	200
3.00	CPTW35153	CPTW35154	CPTW35155	CPTW35156				
4.00	CPTW35157	CPTW35158	CPTW35159	CPTW35160	CPTW35161	CPTW35162	CPTW35163	CPTW35164
5.00	CPTW35165	CPTW35166	CPTW35167	CPTW35168	CPTW35169	CPTW35170	CPTW35171	CPTW35172
6.00	CPTW35173	CPTW35174	CPTW35175	CPTW35176	CPTW35177	CPTW35178	CPTW35179	CPTW35180
7.00	CPTW35181	CPTW35182	CPTW35183	CPTW35184	CPTW35185	CPTW35186	CPTW35187	CPTW35188
8.00	CPTW35189	CPTW35190	CPTW35191	CPTW35192	CPTW35193	CPTW35194	CPTW35195	CPTW35196
9.00	CPTW35197	CPTW35198	CPTW35199	CPTW35200				
10.00	CPTW35201	CPTW35202	CPTW35203	CPTW35204				
12.00	CPTW35205	CPTW35206	CPTW35207	CPTW35208				

Balloon Diameter (mm)	Catheter Length (Shaft Length): 150 cm/1500 mm							
	Balloon Length (mm)							
	20	40	60	80	100	120	150	200
3.00	CPTW35209	CPTW35210	CPTW35211	CPTW35212				
4.00	CPTW35213	CPTW35214	CPTW35215	CPTW35216	CPTW35217	CPTW35218	CPTW35219	CPTW35220
5.00	CPTW35221	CPTW35222	CPTW35223	CPTW35224	CPTW35225	CPTW35226	CPTW35227	CPTW35228
6.00	CPTW35229	CPTW35230	CPTW35231	CPTW35232	CPTW35233	CPTW35234	CPTW35235	CPTW35236
7.00	CPTW35237	CPTW35238	CPTW35239	CPTW35240	CPTW35241	CPTW35242	CPTW35243	CPTW35244
8.00	CPTW35245	CPTW35246	CPTW35247	CPTW35248	CPTW35249	CPTW35250	CPTW35251	CPTW35252
9.00	CPTW35253	CPTW35254	CPTW35255	CPTW35256				
10.00	CPTW35257	CPTW35258	CPTW35259	CPTW35260				
12.00	CPTW35261	CPTW35262	CPTW35263	CPTW35264				



Issued under the Contract No. MD-09/2019
 Application No: 082/2020
 Certificate bears the qualified signature.
 Warsaw, 27/05/2020