

EU DECLARATION OF CONFORMITY

MANUFACTURER : SIMEKS TIBBI URUNLER SAN. VE TIC. LTD. STI.
REGISTERED TRADE MARK: SIMEKS
CONTACT DETAILS : ISTANBUL ENDUSTRI VE TICARET SERBEST BOLGESI
AYDINLI SB.MAH. 10.SOK. NO:5 TUZLA, ISTANBUL,34953-TURKEY

PRODUCT :SIMVALVE PTV BALLOON CATHETER
(SIMVALVE FLEX, SIMVALVE FORCE)

PRODUCT INFORMATION : INTENDED USE AND STANDART LIST IS GIVEN IN ANNEX I
PRODUCT LIST IS GIVEN IN ANNEX II

CLASSIFICATION : CLASS III, RULE 6, ANNEX IX OF MDD 93/42/EEC AMENDED BY
2007/47/EC

NOTIFIED BODY : UDEM ULUSLARARASI BELGELENDIRME DENETIM EGITIM MERKEZI
SANAYI VE TICARET LIMITED SİRKETİ-(IDENTIFICATION NUMBER: 2292)
MUTLUKENT MAHALLESİ 2073 SOKAK NO:10 UMITKOY- CANKAYA

CONFORMITY ASSESSMENT ROUTE : ANNEX II INCLUDING SECTION 4 (MDD 93/42/EEC AMENDED BY
2007/47/EC)

GMDN CODE : 17453

NUMBER OF CERTIFICATES : M.2019.106.12884 / M.2019.106.12884 -1

THE START/VALIDITY DATES OF CERTIFICATES : 04.11.2019 / 27.05.2024

THIS DECLARATION OF CONFORMITY IS ISSUED UNDER THE SOLE RESPONSIBILITY OF SIMEKS TIBBI URUNLER SAN. VE TIC. LTD. STI. THE DEVICE COVERED BY THE PRESENT EU DECLARATION IS IN CONFORMITY WITH MDD 93/42/EEC AMENDED BY 2007/47/EC.

PLACE, DATE OF ISSUE : ISTANBUL, 24.05.2024

NAME/FUNCTION/SIGNATURE: ALPAR ERDOGAN
GENERAL MANAGER

Simeks
TIBBİ ÜRÜNLER SANAYİ VE
TİCARET LİMİTED SİRKETİ
İstanbul Endüstri ve Ticaret Serbest Bölgesi, Aydınli Serbest
Bölge Mah. 10 Sok. No:5 34953 Tuzla/İSTANBUL
Tic Sic. No:412239 Anadoluhisari Kurumları V.D. 770 019 6995

ANNEX I-SIMVALVE PTV BALLOON CATHETER

INTENDED USE

1. Recommended for Percutaneous Transluminal Valvuloplasty (PTV) for aortic position. The use of this catheter is particularly indicated in stenosis where difficulty in balloon positioning during inflation is experienced.
2. Recommended for Percutaneous Transluminal Valvuloplasty (PTV) of the pulmonary valve.
 - A patient with isolated pulmonary stenosis.
 - A patient with valvular pulmonary stenosis with other minor congenital heart disease that does not require surgical intervention.

STANDARDS APPLIED

EN ISO 14971:2019	MDCG 2018-1 Rev.4 :2021
EN ISO 14971:2019/A11:2021	MDCG 2018-2
EN ISO 13485:2016	MDCG 2018-6
EN ISO 13485:2016/AC:2018	MDCG 2018-7
EN ISO 13485:2016/A11:2021	MDCG 2019-1
EN ISO 11737-1:2018	MDCG 2019-4
EN ISO 11737-1:2018/A1:2021	MDCG 2019-5
EN ISO 11737-2:2020	MDCG 2019-7 Rev 1:2023
EN ISO 15223-1:2021	MDCG 2019-9-Rev1:2022
EN ISO 11135:2014	MDCG 2020-3 Rev1:2023
EN ISO 11135:2014/A1:2019	MDCG 2020-6
EN ISO 10993-10:2023	MDCG 2020-7
EN ISO 11607-1:2020/A1:2023	MDCG 2020-8
EN ISO 11607-2:2020/A1:2023	MDCG 2020-10/1 Rev1:2022
EN ISO 10993-18:2020/A1:2023	MDCG 2020-10/2
EN ISO 10993-23:2021	MDCG 2020-13
TS EN ISO 14155:2020	MDCG 2020-15
TS EN 20417:2021	MDCG 2021-1 Rev.1:2021
TS EN ISO 10993-1:2021	MDCG 2021-5
TS EN ISO 10993-2:2022	MDCG 2021-8
TS EN ISO 10993-4:2020	MDCG 2021-6 Rev1: 2023
TS EN ISO 10993-5:2010+D1:2020	MDCG 2021-12
TS EN ISO 10993-7:2010+AC:2010+A1:2022	MDCG 2021-19
TS EN ISO 10993-11:2018	MDCG 2021-20
TS EN ISO 10993-12:2021	MDCG 2021-24
TS EN ISO 10555-1:2013+A1:2018	MDCG 2021-25
TS EN ISO 10555-4:2013	MDCG 2021-27-Rev1:2023
TS EN ISO 80369-7:2021	MDCG 2021-28
TS EN 17141:2020	MDCD 2022-7
TS EN ISO 80369-20:2015	MDCG 2022-9 rev.1
TS EN 62366-1: 2015+ A1:2020+ AC:2016+ AC:2018	MDCD 2022-11
MEDDEV 2.12/1-Rev8-2013	MDCG 2022-18
MEDDEV 2.7/1-Rev4-2016	MDCG 2022-18-ADD1:2023
MEDDEV 2.12/2-Rev2-2012	MDCG 2022-21
ASTM D5276-19	MDCG 2023-3
ASTM F640-23	2023/C 163/06
ASTM F1929-15	Q&A Rev. 1
ASTM F1886/ F1886M – 16	MDCG 2024-3+ Appendix A
ISO/TR 20416:2020	MDCG 2024-5 + Appendix A
ASTM 1980-21	

ANNEX II- SIMVALVE PTV BALLOON CATHETER

SIMVALVE FLEX PTV BALLOON CATHETER

Balloon Dia. (mm)	Balloon Length (mm)				
	20	30	40	50	60
4,0	SVX0420	SVX0430			
5,0	SVX0520	SVX0530			
6,0	SVX0620	SVX0630			
7,0	SVX0720	SVX0730			
8,0	SVX0820	SVX0830			
9,0	SVX0920	SVX0930			
10,0	SVX1020	SVX1030	SVX1040		
12,0	SVX1220	SVX1230	SVX1240	SVX1250	SVX1260
14,0	SVX1420	SVX1430	SVX1440	SVX1450	SVX1460
16,0	SVX1620	SVX1630	SVX1640	SVX1650	SVX1660
18,0	SVX1820	SVX1830	SVX1840	SVX1850	SVX1860
20,0	SVX2020	SVX2030	SVX2040	SVX2050	SVX2060
22,0	SVX2220	SVX2230	SVX2240	SVX2250	SVX2260
24,0	SVX2420	SVX2430	SVX2440	SVX2450	SVX2460
26,0	SVX2620	SVX2630	SVX2640	SVX2650	SVX2660
28,0	SVX2820	SVX2830	SVX2840	SVX2850	SVX2860
30,0	SVX3020	SVX3030	SVX3040	SVX3050	SVX3060

SIMVALVE FORCE PTV BALLOON CATHETER

Balloon Dia. (mm)	Balloon Length (mm)				
	20	30	40	50	60
4,0	SVF0420	SVF0430			
5,0	SVF0520	SVF0530			
6,0	SVF0620	SVF0630			
7,0	SVF0720	SVF0730			
8,0	SVF0820	SVF0830			
9,0	SVF0920	SVF0930			
10,0	SVF1020	SVF1030	SVF1040		
12,0	SVF1220	SVF1230	SVF1240	SVF1250	SVF1260
14,0	SVF1420	SVF1430	SVF1440	SVF1450	SVF1460
16,0	SVF1620	SVF1630	SVF1640	SVF1650	SVF1660
18,0	SVF1820	SVF1830	SVF1840	SVF1850	SVF1860
20,0	SVF2020	SVF2030	SVF2040	SVF2050	SVF2060
22,0	SVF2220	SVF2230	SVF2240	SVF2250	SVF2260
24,0	SVF2420	SVF2430	SVF2440	SVF2450	SVF2460
26,0	SVF2620	SVF2630	SVF2640	SVF2650	SVF2660
28,0	SVF2820	SVF2830	SVF2840	SVF2850	SVF2860
30,0	SVF3020	SVF3030	SVF3040	SVF3050	SVF3060