



CERTIFICATE

EC Design-Examination Certificate

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

With the expire of the certificate M.2019.106.12884 the validity of the certificate M.2019.106.12884-1 will also end.

Company Name : Simeks Tıbbi Ürünler Sanayi ve Ticaret Limited Sirketi

Company Address : İstanbul Endüstri ve Ticaret Serbest Bölgesi Aydınli SB Mah. 10. Sk. No:5
Tuzla 34953 İSTANBUL / TURKEY

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

Product : Sterile PTV Balloon Catheter - Sınıf III

GMDN : 17453

Product Types are attached.

Certificate Number : M.2019.106.12884-1

Report Number : MD.3753.IB

Initial Assessment Date : 24.05.2019

Registration Date : 04.11.2019

Revision Date /No : -

Expiry Date : 27.05.2024

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

The EC design 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 applied 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 validity 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.

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SimValve Flex PTV Balloon Catheter					
Balloon Diameter (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 Diameter (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