



CERTIFICATE

EC No. 1434-MDD-041/2019
Full Quality Assurance System

Directive 93/42/EEC concerning medical devices

Polish Centre for Testing and Certification certifies,
that the quality assurance system in the organization:

VUP Medical a.s.
Sujanovo nam. 3
602 00 Brno, Czech Republic

for the design, manufacture and final inspection of medical device
class III

Knitted vascular patch with collagen Ra ZK
Knitted vascular prosthesis with collagen Ra K
Knitted vascular prosthesis with collagen Ra K Incompressible

*The list of medical devices covered by this certificate is given in Annexes No. 1 and 2 to the
Certificate no. 1434-MDD-040/2019.*

complies with requirements

of Annex II excluding 4 to Directive 93/42/EEC (as amended) implemented into Polish law, as evidenced by the
audit conducted by the PCBC.

Validity of Certificate: from 08-03-2019 to 15-10-2022

The date of issue of the Certificate: 08-03-2019

The date of the first issue of the Certificate: 16-10-2017



Application No: 103-1/2016
Module: H2


mgr Anna Wyroba
Vice-President



ANNEX NO. 1 TO CERTIFICATE
VALID ONLY WITH CERTIFICATE
No. 1434-MDD-040/2019

The list of medical devices which are certified

<i>Knitted vascular patch with collagen Ra ZK</i>		
Width (mm)	Length (mm)	Catalogue number
13	80	020-1380
35	100	020-3510
8	75	020-0875
13	100	020-1310

<i>Knitted vascular prosthesis with collagen Ra K bifurcated</i>		
Length (mm)	Diameter (D1/D2) (mm)	Catalogue number
400	6/12	024-0612
	7/14	024-0714
	8/16	024-0816
	9/18	024-0918
	10/20	024-1020
	11/22	024-1122

<i>Knitted vascular prosthesis with collagen Ra K incompressible</i>				
Diameter (D) (mm)	Catalogue number			
	Length (L) 250 mm	Length (L) 500 mm	Length (L) 600 mm	Length (L) 700 mm
6	026-0061	026-0062	026-0063	026-0064
7	026-0071	026-0072	026-0073	026-0074
8	026-0081	026-0082	026-0083	-
9	026-0091	026-0092	026-0093	-
12	026-0121	026-0122	026-0123	-



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Vice-President



ANNEX NO. 2 TO CERTIFICATE
VALID ONLY WITH CERTIFICATE
No. 1434-MDD-040/2019

The list of medical devices which are certified

<i>Knitted vascular prosthesis with collagen Ra K</i>					
Length (L) (mm)	Diameter (D) (mm)	Catalogue number	Length (L) (mm)	Diameter (D) (mm)	Catalogue number
250	6	022-0061	500	6	022-0062
	7	022-0071		7	022-0072
	8	022-0081		8	022-0082
	9	022-0091		9	022-0092
	10	022-0101		10	022-0102
	12	022-0121		12	022-0122
	14	022-0141		14	022-0142
	16	022-0161		16	022-0162
	18	022-0181		18	022-0182
	20	022-0201		20	022-0202
	22	022-0221		22	022-0222
	24	022-0241		24	022-0242
	25	022-0251		25	022-0252
	26	022-0261		26	022-0262
	28	022-0281		28	022-0282
	30	022-0301		30	022-0302
	32	022-0321		32	022-0322
	34	022-0341		34	022-0342

<i>Knitted vascular prosthesis with collagen Ra K, Ra K bifurcated, Ra K incompressible</i>		
Length (30-700) mm	Diameter (6-34) mm	made to order



Anna Wyróba
mgr Anna Wyróba
Vice-President



CERTIFICATE

EC No. 1434-MDD-040/2019
EC Design-Examination

Directive 93/42/EEC concerning medical devices

Polish Centre for Testing and Certification certifies,
that the documentation submitted by:

VUP Medical a.s.
Sujanovo nam. 3
602 00 Brno, Czech Republic

related to the medical device
class III

Knitted vascular patch with collagen Ra ZK
Knitted vascular prosthesis with collagen Ra K
Knitted vascular prosthesis with collagen Ra K Incompressible

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Application No: 103-1/2016
Module: H1


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