



Gelweave™

 **TERUMO**
Aortic

Product Ordering Information

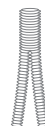
Straights

BORE SIZE mm	USABLE LENGTH cm	CATALOGUE NUMBER
6	15	731506
6	30	733006
6	60	736006
8	15	731508
8	30	733008
8	60	736008
10	15	731510
10	30	733010
10	60	736010
12	15	731512
12	30	733012
12	60	736012
14	15	731514
14	30	733014
14	60	736014
16	15	731516
16	30	733016
16	60	736016
18	12	731218
18	25	732518
18	50	735018
20	12	731220
20	25	732520
20	50	735020
22	12	731222
22	25	732522
22	50	735022
24	12	731224
24	25	732524
24	50	735024
26	12	731226
26	25	732526
26	50	735026
28	12	731228
28	25	732528
28	50	735028
30	10	731030
30	20	732030
30	40	734030
32	10	731032
32	20	732032
32	40	734032
34	10	731034
34	20	732034
34	40	734034
36	30	733036
36	40	734036
36	60	736036
38	10	731038
38	20	732038
38	40	734038



Bifurcates

BORE SIZE mm	USABLE LENGTH cm	CATALOGUE NUMBER
12 x 6	45	731206
14 x 7	45	731407
16 x 8	45	731608
18 x 9	45	731809
20 x 10	45	732010
22 x 11	45	732211
24 x 12	45	732412



Also available in single and multibranch designs

- ✓ Unique hydrolysable gelatin impregnation ¹
- ✓ Proven Twillweave™ base fabric ²
- ✓ Superb handling
- ✓ Excellent suture retention ²
- ✓ Cardiothoracic and abdominal applications ²

References

1. Drury J *et al* (1987). Experimental and Clinical Experience with a Gelatin Impregnated Dacron Prosthesis. *Ann Vasc Surg*, 1, 542-547.
2. Data & clinical information on file at Vascutek Ltd.

TERUMO
Aortic

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Declaration of Conformity Record

Manufacturer's Name: Vascutek Ltd, a TERUMO Company**Manufacturer's Address:** Newmains Avenue, Inchinnan, Renfrewshire PA4 9RR Scotland**Product Family:** Woven Vascular Grafts**Product Class:** Class III**Product Range: Twillweave Vascular Grafts**Straight
Bifurcate**Gelweave Vascular Grafts**Straight
Bifurcate
Trifurcate
Trifurcate with Side Branch With or Without Radiopaque Marker
Double Bifurcates
Curved Graft
Curved Ante-Flo
Precurved 4 Branch Plexus
Ante-Flo
Trifurcate Arch Graft
Thoracic Arch Graft with or Without Radiopaque Marker
Three Branch Plexus
Aortic Arch
Trifurcate Arch Graft with Side Branch
Four Branch Plexus
Plexus (With Extra Black Line)
Thoracoabdominal
Aortic Arch Trifurcate Graft
Branched Arch Graft With or without Radiopaque Markers
Ante-flo with Collar
Four Branch Plexus with Collar
Siena Collared Straight with Radiopaque Markers
Siena Collared Ante-flo with Radiopaque Markers
Siena Collared Four Branch Plexus with Radiopaque Markers
Valsalva
Valsalva with Collar
Valsalva + Ante-Flo**Revision Number:** EUDOC-001W-001

I, the undersigned, hereby declare that the medical device(s) specified above conforms with the Essential Requirements listed in Annex I of EC Directive 93/42/EEC.

This declaration is supported by:

EC Quality System approval statement (Annex II) No.: **CE00422**

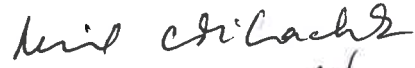
Issued by:	BSI Netherlands (NB No: 2797) *	First Issued On:	21/12/94
Current Issue No.:	18	Dated:	05/02/19

EC Design Dossier examination No. **CE00514, CE01230**

Issued by:	BSI Netherlands (NB No: 2797) *	First Issued On:	14/02/95, 06/03/96
Current Issue No.:	23, 10	Dated:	05/02/19, 05/02/19

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*Previous issues of these certificates were issued by BSI UK (NB No: 0086). Vascutek completed Notified Body migration from BSI UK to BSI Netherlands in February 2019 as part of preparations for the UK leaving the EU.

Signed: 
Name: Neil McLACHLAN

Date: 23 APRIL 2019

VP Regulatory Affairs

Declaration of Conformity Record

Catalogue Numbers Covered by Attached Woven Vascular Grafts Declaration of Conformity

CE01230 TWILLWEAVE VASCULAR GRAFTS

RANGE: TWILLWEAVE STRAIGHTS		
SIZE	CATALOGUE NUMBER	USABLE LENGTH
6 mm	536006	60 cm
7 mm	536007	60 cm
8 mm	536008	60 cm
9 mm	536009	60 cm
10 mm	536010	60 cm
11 mm	536011	60 cm
12 mm	536012	60 cm
14 mm	536014	60 cm
16 mm	536016	60 cm
18 mm	536018	60 cm
20 mm	536020	60 cm
22 mm	536022	60 cm
24 mm	536024	60 cm
26 mm	536026	60 cm
28 mm	536028	60 cm
30 mm	536030	60 cm
32 mm	536032	60 cm
34 mm	536034	60 cm
36 mm	536036	60 cm
38 mm	536038	60 cm
18 mm	535018	50 cm
20 mm	535020	50 cm
22 mm	535022	50 cm
24 mm	535024	50 cm
26 mm	535026	50 cm
28 mm	535028	50 cm
30 mm	534030	40 cm
32 mm	534032	40 cm
34 mm	534034	40 cm
36 mm	534036	40 cm
38 mm	534038	40 cm
6 mm	533006	30 cm
7 mm	533007	30 cm
8 mm	533008	30 cm
9 mm	533009	30 cm
10 mm	533010	30 cm
11 mm	533011	30 cm
12 mm	533012	30 cm
14 mm	533014	30 cm
16 mm	533016	30 cm
18 mm	533018	30 cm
20 mm	533020	30 cm
22 mm	533022	30 cm
24 mm	533024	30 cm
26 mm	533026	30 cm
28 mm	533028	30 cm
30 mm	533030	30 cm
32 mm	533032	30 cm
34 mm	533034	30 cm
36 mm	533036	30 cm
38 mm	533038	30 cm

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RANGE: TWILLWEAVE STRAIGHTS		
SIZE	CATALOGUE NUMBER	USABLE LENGTH
18 mm	532518	25 cm
20 mm	532520	25 cm
22 mm	532522	25 cm
24 mm	532524	25 cm
26 mm	532526	25 cm
28 mm	532528	25 cm
30 mm	532030	20 cm
32 mm	532032	20 cm
34 mm	532034	20 cm
36 mm	532036	20 cm
38 mm	532038	20 cm
6 mm	531506	15 cm
7 mm	531507	15 cm
8 mm	531508	15 cm
9 mm	531509	15 cm
10 mm	531510	15 cm
11 mm	531511	15 cm
12 mm	531512	15 cm
14 mm	531514	15 cm
16 mm	531516	15 cm
18 mm	531218	12.5 cm
20 mm	531220	12.5 cm
22 mm	531222	12.5 cm
24 mm	531224	12.5 cm
26 mm	531226	12.5 cm
28 mm	531228	12.5 cm
30 mm	531030	10 cm
32 mm	531032	10 cm
34 mm	531034	10 cm
36 mm	531036	10 cm
38 mm	531038	10 cm

RANGE: TWILLWEAVE BIFURCATES		
SIZE	CATALOGUE NUMBER	USABLE LENGTH
12 x 6 mm	531206	45 cm
14 x 7 mm	531407	45 cm
16 x 8 mm	531608	45 cm
18 x 9 mm	531809	45 cm
20 x 10 mm	532010	45 cm
22 x 11 mm	532211	45 cm
24 x 12 mm	532412	45 cm

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RANGE: UNCRIMPED TWILLWEAVE STRAIGHTS		
SIZE	CATALOGUE NUMBER	USABLE LENGTH
14 mm	553014	30 cm
16 mm	553016	30 cm
18 mm	553018	30 cm
20 mm	553020	30 cm
24 mm	553024	30 cm
26 mm	553026	30 cm
28 mm	553028	30 cm
30 mm	553030	30 cm
32 mm	553032	30 cm
34 mm	553034	30 cm
36 mm	553036	30 cm
38 mm	553038	30 cm
14 mm	555014	50 cm
16 mm	555016	50 cm
18 mm	555018	50 cm
20 mm	555020	50 cm
22 mm	555022	50 cm
24 mm	555024	50 cm
26 mm	555026	50 cm
28 mm	555028	50 cm
30 mm	555030	50 cm
32 mm	555032	50 cm
34 mm	555034	50 cm
36 mm	555036	50 cm
38 mm	555038	50 cm

RANGE: UNCRIMPED TWILLWEAVE BIFURCATES		
SIZE	CATALOGUE NUMBER	USABLE LENGTH
12 x 6 mm	551206	45 cm
14 x 7 mm	551407	45 cm
16 x 8 mm	551608	45 cm
18 x 9 mm	551809	45 cm
20 x 10 mm	552010	45 cm
22 x 11 mm	552211	45 cm
24 x 12 mm	552412	45 cm

SEALED GRAFTS: WOVEN – GELWEAVE

The base fabric for Gelweave is Twillweave

RANGE: GELWEAVE STRAIGHTS		
SIZE	CATALOGUE NUMBER	USABLE LENGTH
6 mm	736006	60 cm
7 mm	736007	60 cm
8 mm	736008	60 cm
9 mm	736009	60 cm
10 mm	736010	60 cm
11 mm	736011	60 cm
12 mm	736012	60 cm
14 mm	736014	60 cm
16 mm	736016	60 cm
6 mm	734006	40 cm
8 mm	734008	40 cm
6 mm	733006	30 cm
7 mm	733007	30 cm
8 mm	733008	30 cm
9 mm	733009	30 cm
10 mm	733010	30 cm
11 mm	733011	30 cm
12 mm	733012	30 cm
14 mm	733014	30 cm

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16 mm	733016	30 cm
6 mm	731506	15 cm
7 mm	731507	15 cm
8 mm	731508	15 cm
9 mm	731509	15 cm
10 mm	731510	15 cm
11 mm	731511	15 cm
12 mm	731512	15 cm
14 mm	731514	15 cm
16 mm	731516	15 cm
18 mm	735018	50 cm
20 mm	735020	50 cm
22 mm	735022	50 cm
24 mm	735024	50 cm
26 mm	735026	50 cm
28 mm	735028	50 cm
30 mm	735030	50 cm
32 mm	735032	50 cm
34mm	735034	50 cm
26 mm	730526	5 cm
28 mm	730528	5 cm
18 mm	732518	25 cm
20 mm	732520	25 cm
22 mm	732522	25 cm
24 mm	732524	25 cm
26 mm	732526	25 cm
28 mm	732528	25 cm
18 mm	731218	12.5 cm
20 mm	731220	12.5 cm
22 mm	731222	12.5 cm
24 mm	731224	12.5 cm
26 mm	731226	12.5 cm
28 mm	731228	12.5 cm
18 mm	733018	30 cm
20 mm	733020	30 cm
22 mm	733022	30 cm
24 mm	733024	30 cm
26 mm	733026	30 cm
28 mm	733028	30 cm
30 mm	733030	30 cm
32 mm	733032	30 cm
34 mm	733034	30 cm
36 mm	733036	30 cm
38 mm	733038	30 cm
30 mm	731030	10 cm
32 mm	731032	10 cm
34 mm	731034	10 cm
38 mm	731038	10 cm
30 mm	732030	20 cm
32 mm	732032	20 cm
34 mm	732034	20 cm
38 mm	732038	20 cm

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30 mm	734030	40 cm
32 mm	734032	40 cm
34 mm	734034	40 cm
36 mm	734036	40 cm
38 mm	734038	40 cm
18 mm	736018	60 cm
20 mm	736020	60 cm
22 mm	736022	60 cm
24 mm	736024	60 cm
26 mm	736026	60 cm
28 mm	736028	60 cm
30 mm	736030	60 cm
32 mm	736032	60 cm
34 mm	736034	60 cm
36 mm	736036	60 cm
38 mm	736038	60 cm
24 mm	7310024	100 cm
26 mm	7310026	100 cm
28 mm	7310028	100 cm

RANGE: GELWEAVE STRAIGHTS WITH 3 BLACK LINES (VS192)

SIZE	CATALOGUE NUMBER	USABLE LENGTH
18 mm	7312183BL	12.5 cm
20 mm	7312203BL	12.5 cm
22 mm	7312223BL	12.5 cm
24 mm	7312243BL	12.5 cm
26 mm	7312263BL	12.5 cm
28 mm	7312283BL	12.5 cm
18 mm	7325183BL	25 cm
20 mm	7325203BL	25 cm
22 mm	7325223BL	25 cm
24 mm	7325243BL	25 cm
26 mm	7325263BL	25 cm
28 mm	7325283BL	25 cm
18 mm	7350183BL	50 cm
20 mm	7350203BL	50 cm
22 mm	7350223BL	50 cm
30 mm	7310303BL	10 cm
30 mm	7320303BL	20 cm
30 mm	7340303BL	40 cm

RANGE: GELWEAVE BIFURCATES

SIZE	CATALOGUE NUMBER	USABLE LENGTH
12 x 6 mm	731206	45 cm
14 x 7 mm	731407	45 cm
16 x 8 mm	731608	45 cm
18 x 9 mm	731809	45 cm
20 x 10 mm	732010	45 cm
22 x 11 mm	732211	45 cm
24 x 12 mm	732412	45 cm

RANGE: GELWEAVE TRIFURCATE

SIZE	CATALOGUE NUMBER	USABLE LENGTH
12 x 6 x 6 x 7 mm	731206/7	45 cm
14 x 7 x 7 x 7 mm	731407/7	45 cm
16 x 8 x 8 x 7 mm	731608/7	45 cm

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RANGE: GELWEAVE TRIFURCATE WITH SIDE BRANCH		
SIZE	CATALOGUE NUMBER	USABLE LENGTH
12 x 10 x 6 x 6 x 10 mm	731206/10/10	45 cm + 1 @ 15cm
14 x 10 x 7 x 7 x 10 mm	731407/10/10	45 cm + 1 @ 15cm
16 x 10 x 8 x 8 x 10 mm	731608/10/10	45 cm + 1 @ 15cm
16 x 8 x 8 x 8 x 10 mm	731608/8/10	45 cm + 1 @ 15cm

RANGE: GELWEAVE™ TRIFURCATE WITH SIDE BRANCH WITH RADIOPAQUE MARKER		
SIZE	CATALOGUE NUMBER	USABLE LENGTH
12/10/6/6 x 10mm	731206/10/10RM	45 cm + 1 @ 15cm
14/10/7/7 x 10mm	731407/10/10RM	45 cm + 1 @ 15cm
16/10/8/8 x 10mm	731608/10/10RM	45 cm + 1 @ 15cm
16/8/8/8 x 10mm	731608/8/10RM	45 cm + 1 @ 15cm

RANGE: GELWEAVE DOUBLE BIFURCATES		
SIZE	CATALOGUE NUMBER	USABLE LENGTH
16 x 7 x 8 mm	731607DB8	45 cm
18 x 8 x 9 mm	731808DB9	45 cm
20 x 9 x 10 mm	732009DB10	45 cm

RANGE: GELWEAVE EXTRA LONG BIFURCATES				
CATALOGUE NUMBER	GRAFT DIAMETER	BODY LENGTH	LEG LENGTH	USEABLE LENGTH
731206XL55	12 x 6mm	10cm	45cm	55cm
731407XL55	14 x 7mm	10cm	45cm	55cm
731608XL55	16 x 8mm	10cm	45cm	55cm
731809XL55	18 x 9mm	10cm	45cm	55cm
732010XL55	20 x 10mm	10cm	45cm	55cm
732211XL55	22 x 11mm	10cm	45cm	55cm
732412XL55	24 x 12mm	10cm	45cm	55cm

RANGE: GELWEAVE CURVED GRAFT		
SIZE	CATALOGUE NUMBER	USABLE LENGTH
22 mm	735022ST	50 cm
24 mm	735024ST	50 cm
26 mm	735026ST	50 cm
28 mm	735028ST	50 cm
30 mm	735030ST	50 cm
32 mm	735032ST	50 cm
34 mm	735034ST	50 cm

RANGE: GELWEAVE CURVED ANTE-FLO GRAFT OFFSET BRANCH		
SIZE	CATALOGUE NUMBER	USABLE LENGTH
26 x 8 mm	735026ST/8	50cm + 1 @ 15 cm
28 x 8 mm	735028ST/8	50cm + 1 @ 15 cm
30 x 8 mm	735030ST/8	50cm + 1 @ 15 cm

RANGE: GELWEAVE™ PRE-CURVED ANTE-FLO		
SIZE	CATALOGUE NUMBER	USABLE LENGTH
22 x 8mm	735022ST/8B	50cm + 1 @ 15cm
24 x 8mm	735024ST/8B	50cm + 1 @ 15cm
26 x 8mm	735026ST/8B	50cm + 1 @ 15cm
28 x 8mm	735028ST/8B	50cm + 1 @ 15cm
30 x 8mm	735030ST/8B	50cm + 1 @ 15cm
32 x 8mm	735032ST/8B	50cm + 1 @ 15cm
34 x 8mm	735034ST/8B	50cm + 1 @ 15cm
22 x 10mm	735022ST/10B	50cm + 1 @ 15cm
24 x 10mm	735024ST/10B	50cm + 1 @ 15cm
26 x 10mm	735026ST/10B	50cm + 1 @ 15cm
28 x 10mm	735028ST/10B	50cm + 1 @ 15cm

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30 x 10mm	735030ST/10B	50cm + 1 @ 15cm
32 x 10mm	735032ST/10B	50cm + 1 @ 15cm
34 x 10mm	735034ST/10B	50cm + 1 @ 15cm
22 x 8 mm	735022ST/8A	50cm + 1 @ 15cm
24 x 8 mm	735024ST/8A	50cm + 1 @ 15cm
26 x 8 mm	735026ST/8A	50cm + 1 @ 15cm
28 x 8 mm	735028ST/8A	50cm + 1 @ 15cm
30 x 8 mm	735030ST/8A	50cm + 1 @ 15cm
32 x 8 mm	735032ST/8A	50cm + 1 @ 15cm
34 x 8 mm	735034ST/8A	50cm + 1 @ 15cm

RANGE: GELWEAVE™ PRECURVED 4 BRANCH PLEXUS		
SIZE	CATALOGUE NUMBER	USABLE LENGTH
20/12/8/10 x 10mm	732012810/10STA	40cm + 4 @ 15cm
22/12/8/10 x 10mm	732212810/10STA	40cm + 4 @ 15cm
24/12/8/10 x 10mm	732412810/10STA	40cm + 4 @ 15cm
26/12/8/10 x 10mm	732612810/10STA	40cm + 4 @ 15cm
28/12/8/10 x 10mm	732812810/10STA	40cm + 4 @ 15cm
30/12/8/10 x 10mm	733012810/10STA	40cm + 4 @ 15cm
32/12/8/10 x 10mm	733212810/10STA	40cm + 4 @ 15cm
34/12/8/10 x 10mm	733412810/10STA	40cm + 4 @ 15cm
20/10/8/8 x 10mm	73201088/10STA	40cm + 4 @ 15cm
22/10/8/8 x 10mm	73221088/10STA	40cm + 4 @ 15cm
24/10/8/8 x 10mm	73241088/10STA	40cm + 4 @ 15cm
26/10/8/8 x 10mm	73261088/10STA	40cm + 4 @ 15cm
28/10/8/8 x 10mm	73281088/10STA	40cm + 4 @ 15cm
30/10/8/8 x 10mm	73301088/10STA	40cm + 4 @ 15cm
32/10/8/8 x 10mm	73321088/10STA	40cm + 4 @ 15cm
34/10/8/8 x 10mm	73341088/10STA	40cm + 4 @ 15cm
20/10/8/8 x 8mm	73201088/8SD	40cm + 4 @ 15cm
22/10/8/8 x 8mm	73221088/8SD	40cm + 4 @ 15cm
24/10/8/8 x 8mm	73241088/8SD	40cm + 4 @ 15cm
26/10/8/8 x 8mm	73261088/8SD	40cm + 4 @ 15cm
28/10/8/8 x 8mm	73281088/8SD	40cm + 4 @ 15cm
30/10/8/8 x 8mm	73301088/8SD	40cm + 4 @ 15cm
32/10/8/8 x 8mm	73321088/8SD	40cm + 4 @ 15cm
34/10/8/8 x 8mm	73341088/8SD	40cm + 4 @ 15cm

RANGE: GELWEAVE ANTE-FLO		
SIZE	CATALOGUE NUMBER	USABLE LENGTH
18 x 8mm	734018/8	40cm + 1 @ 15cm
20 x 8 mm	734020/8	40cm + 1 @ 15cm
22 x 8 mm	734022/8	40cm + 1 @ 15cm
24 x 8 mm	734024/8	40cm + 1 @ 15cm
26 x 8 mm	734026/8	40cm + 1 @ 15cm
28 x 8 mm	734028/8	40cm + 1 @ 15cm
30 x 8 mm	734030/8	40cm + 1 @ 15cm
32 x 8 mm	734032/8	40cm + 1 @ 15cm
34 x 8 mm	734034/8	40cm + 1 @ 15cm
22 x 8 mm	732022/8	20cm + 1 @ 15cm
24 x 8 mm	732024/8	20cm + 1 @ 15cm
26 x 8 mm	732026/8	20cm + 1 @ 15cm
28 x 8 mm	732028/8	20cm + 1 @ 15cm
30 x 8 mm	732030/8	20cm + 1 @ 15cm
32 x 8 mm	732032/8	20cm + 1 @ 15cm
34 x 8 mm	732034/8	20cm + 1 @ 15cm
24 x 10 mm	735024/10	50cm + 1 @ 15cm
28 x 10 mm	735028/10	50cm + 1 @ 15cm

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32 x 10 mm	735032/10	50cm + 1@15cm
20 x 10 mm	734020/10	40cm + 1@15cm
22 x 10 mm	734022/10	40cm + 1@15cm
22 x 10 mm	734022/10S	40cm + 1@15cm
24 x 10 mm	734024/10	40cm + 1@15cm
24 x 10 mm	734024/10S	40cm + 1@25cm
26 x 10 mm	734026/10	40cm + 1@15cm
26 x 10 mm	734026/10S	40cm + 1@25cm
28 x 10 mm	734028/10	40cm + 1@15cm
28 x 10 mm	734028/10S	40cm + 1@25cm
30 x 10 mm	734030/10	40cm + 1@15cm
20 x 10 mm	734020/10S	40cm + 1@25cm
30 x 10 mm	734030/10S	40cm + 1@25cm
32 x 10 mm	734032/10	40cm + 1@15cm
34 x 10 mm	734034/10	40cm + 1@15cm
22 x 10 mm	732022/10	20cm + 1@15cm
24 x 10 mm	732024/10	20cm + 1@15cm
26 x 10 mm	732026/10	20cm + 1@15cm
28 x 10 mm	732028/10	20cm + 1@15cm
30 x 10 mm	732030/10	20cm + 1@15cm
32 x 10 mm	732032/10	20cm + 1@15cm
34 x 10 mm	732034/10	20cm + 1@15cm

RANGE: GELWEAVE EXTRA LENGTH ANTE-FLO WITH OFFSET BRANCH		
SIZE	CATALOGUE NUMBER	USABLE LENGTH
22 x 8 mm	735022/8S	50cm + 1@15cm
24 x 8 mm	735024/8S	50cm + 1@15cm
26 x 8 mm	735026/8S	50cm + 1@15cm
28 x 8 mm	735028/8S	50cm + 1@15cm
30 x 8 mm	735030/8S	50cm + 1@15cm
32 x 8 mm	735032/8S	50cm + 1@15cm

RANGE: GELWEAVE™ LONGER ANTE-FLO WITH OFFSET BRANCH (VS076)		
SIZE	CATALOGUE NUMBER	USABLE LENGTH
22 x 8 mm	736022/8S	60 cm + 1@15cm
24 x 8 mm	736024/8S	60 cm + 1@15cm
26 x 8 mm	736026/8S	60 cm + 1@15cm
28 x 8 mm	736028/8S	60 cm + 1@15cm
30 x 8 mm	736030/8S	60 cm + 1@15cm
32 x 8 mm	736032/8S	60 cm + 1@15cm

RANGE: GELWEAVE™ ANTE-FLO WITH OFFSET SIDE BRANCH		
SIZE	CATALOGUE NUMBER	USABLE LENGTH
26 x 10 mm	733026/10S	30cm + 1@15cm
28 x 10 mm	733028/10S	30cm + 1@15cm
30 x 10 mm	733030/10S	30cm + 1@15cm
32 x 10 mm	733032/10S	30cm + 1@15cm
26 x 10 mm	736026/10S	60cm + 1@15cm
28 x 10 mm	736028/10S	60cm + 1@15cm
30 x 10 mm	736030/10S	60cm + 1@15cm
32 x 10 mm	736032/10S	60cm + 1@15cm

RANGE: GELWEAVE TRIFURCATE ARCH GRAFT		
SIZE	CATALOGUE NUMBER	SIZE
12/8/8mm	732012/8X2	20cm+2@10cm
12/10/10mm	732012/10X2	20cm+2@10cm
14/8/8mm	732014/8X2	20cm+2@10cm
14/10/10mm	732014/10X2	20cm+2@10cm

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RANGE: GELWEAVE™ THORACIC ARCH GRAFT		
SIZE	CATALOGUE NUMBER	USABLE LENGTH
14X10X10mm	732214/10/10A	22cm + 10cm + 13cm
12X10X8mm	732212/10/8A	22cm + 10cm + 13cm

RANGE: GELWEAVE™ THORACIC ARCH GRAFT WITH RADIOPAQUE MARKER		
SIZE	CATALOGUE NUMBER	USABLE LENGTH
14X10X10mm	732214/10/10ARM	22cm + 10cm + 13cm
12X10X8mm	732212/10/8ARM	22cm + 10cm + 13cm

RANGE: GELWEAVE –THREE BRANCH PLEXUS		
SIZE	CATALOGUE NUMBER	SIZE
20/10/8/8 mm	73201088	40 cm + 3 @ 15 cm
22/10/8/8 mm	73221088	40 cm + 3 @ 15 cm
24/10/8/8 mm	73241088	40 cm + 3 @ 15 cm
26/10/8/8 mm	73261088	40 cm + 3 @ 15 cm
28/10/8/8 mm	73281088	40 cm + 3 @ 15 cm
30/10/8/8 mm	73301088	40 cm + 3 @ 15 cm
32/10/8/8 mm	73321088	40 cm + 3 @ 15 cm
34/10/8/8 mm	73341088	40 cm + 3 @ 15 cm

RANGE: GELWEAVE™ AORTIC ARCH		
SIZE	CATALOGUE NUMBER	USABLE LENGTH
14/10/10/10mm	732514/10X3	25cm + 3@10cm

RANGE: GELWEAVE™ TRIFURCATE ARCH GRAFT WITH SIDE BRANCH		
SIZE	CATALOGUE NUMBER	USABLE LENGTH
12/10/10X8mm	73128/10X2	30cm + 3@10cm
10/8/8X8mm	73108/8X2	30cm + 3@10cm
10/10/8X8mm	731010/8X2	30cm + 3@10cm
12/10/8X8mm	731210/8X2	30cm + 3@10cm

RANGE: GELWEAVE – FOUR BRANCH PLEXUS		
SIZE	CATALOGUE NUMBER	SIZE
20/10/8/8 x 8 mm	73201088/8	40 cm + 4 @ 15 cm
22/10/8/8 x 8 mm	73221088/8	40 cm + 4 @ 15 cm
24/10/8/8 x 8 mm	73241088/8	40 cm + 4 @ 15 cm
26/10/8/8 x 8 mm	73261088/8	40 cm + 4 @ 15 cm
28/10/8/8 x 8 mm	73281088/8	40 cm + 4 @ 15 cm
30/10/8/8 x 8 mm	73301088/8	40 cm + 4 @ 15 cm
32/10/8/8 x 8 mm	73321088/8	40 cm + 4 @ 15 cm
34/10/8/8 x 8 mm	73341088/8	40 cm + 4 @ 15 cm
20/10/8/8 x 10 mm	73201088/10	40 cm + 4 @ 15 cm
22/10/8/8 x 10 mm	73221088/10	40 cm + 4 @ 15 cm
24/10/8/8 x 10 mm	73241088/10	40 cm + 4 @ 15 cm
26/10/8/8 x 10 mm	73261088/10	40 cm + 4 @ 15 cm
28/10/8/8 x 10 mm	73281088/10	40 cm + 4 @ 15 cm
30/10/8/8 x 10 mm	73301088/10	40 cm + 4 @ 15 cm
32/10/8/8 x 10 mm	73321088/10	40 cm + 4 @ 15 cm
34/10/8/8 x 10 mm	73341088/10	40 cm + 4 @ 15 cm
28/12/8/8X8 mm	73281288/8	40 cm + 4 @ 15 cm

RANGE: GELWEAVE™ PLEXUS (WITH EXTRA BLACK LINE)		
SIZE	CATALOGUE NUMBER	USABLE LENGTH
20/12/8/8X8mm	73201288/8A	40cm + 4@15cm
22/12/8/8X8mm	73221288/8A	40cm + 4@15cm
24/12/8/8X8mm	73241288/8A	40cm + 4@15cm
26/12/8/8X8mm	73261288/8A	40cm + 4@15cm

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28/12/8/8X8mm	73281288/8A	40cm + 4@15cm
30/12/8/8X8mm	73301288/8A	40cm + 4@15cm
32/12/8/8X8mm	73321288/8A	40cm + 4@15cm
34/12/8/8X8mm	73341288/8A	40cm + 4@15cm

RANGE: THORACOABDOMINAL GRAFT		
SIZE	CATALOGUE NUMBER	USABLE LENGTH
26/12/12/12 x12mm	736026/12 x 4	60cm + 4 @ 12 cm
28/12/12/12 x 12mm	736028/12 x 4	60cm + 4 @ 12 cm
20/6/6/8 x 6mm	7320668/6	60cm + 4@10cm
22/6/6/8 x 6mm	7322668/6	60cm + 4@10cm
24/6/6/8 x 6mm	7324668/6	60cm + 4@10cm
26/6/6/8 x 6mm	7326668/6	60cm + 4@10cm
28/6/6/8 x 6mm	7328668/6	60cm + 4@10cm
30/6/6/8 x 6mm	7330668/6	60cm + 4@10cm
20/8/8/8 x 8mm	7320888/8	60cm + 4@10cm
22/8/8/8 x 8mm	7322888/8	60cm + 4@10cm
24/8/8/8 x 8mm	7324888/8	60cm + 4@10cm
26/8/8/8 x 8mm	7326888/8	60cm + 4@10cm
28/8/8/8 x 8mm	7328888/8	60cm + 4@10cm
30/8/8/8 x 8mm	7330888/8	60cm + 4@10cm

RANGE: COSELLI THORACO ABDOMINAL		
SIZE	CATALOGUE NUMBER	USABLE LENGTH
20/10/10/8X8 mm	732010108/8S4	60cm + 4 @ 10 cm
22/10/10/8X8 mm	732210108/8S4	60cm + 4 @ 10 cm
24/10/10/8X8 mm	732410108/8S4	60cm + 4 @ 10 cm
26/10/10/8X8 mm	732610108/8S4	60cm + 4 @ 10 cm
28/10/10/8X8 mm	732810108/8S4	60cm + 4 @ 10 cm
30/10/10/8X8 mm	733010108/8S4	60cm + 4 @ 10 cm

RANGE: GELWEAVE™ AORTIC ARCH TRIFURCATE GRAFT		
SIZE	CATALOGUE NUMBER	USABLE LENGTH
24/12/8/8mm	73248812	15cm + 3@30cm

RANGE: GELWEAVE™ THORACIC ARCH GRAFT		
SIZE	CATALOGUE NUMBER	USABLE LENGTH
22/12/8/8 x 10mm	732022CX4	20cm + 2@15cm + 2@30cm
24/12/8/8 x10mm	732024CX4	20cm + 2@15cm + 2@30cm
26/12/8/8 x 10mm	732026CX4	20cm + 2@15cm + 2@30cm
28/12/8/8 x 10mm	732028CX4	20cm + 2@15cm + 2@30cm
30/12/8/8 x 10mm	732030CX4	20cm + 2@15cm + 2@30cm
32/12/8/8 x 10mm	732032CX4	20cm + 2@15cm + 2@30cm
34/12/8/8 x 10mm	732034CX4	20cm + 2@15cm + 2@30cm

RANGE: GELWEAVE™ BRANCHED ARCH GRAFT WITH RADIOPAQUE MARKERS		
SIZE	CATALOGUE NUMBER	USABLE LENGTH
22/12/8/8 x 10mm	732022CX4RM	20cm + 2@15cm + 2@30cm
24/12/8/8 x10mm	732024CX4RM	20cm + 2@15cm + 2@30cm
26/12/8/8 x 10mm	732026CX4RM	20cm + 2@15cm + 2@30cm
28/12/8/8 x 10mm	732028CX4RM	20cm + 2@15cm + 2@30cm
30/12/8/8 x 10mm	732030CX4RM	20cm + 2@15cm + 2@30cm
32/12/8/8 x 10mm	732032CX4RM	20cm + 2@15cm + 2@30cm
34/12/8/8 x 10mm	732034CX4RM	20cm + 2@15cm + 2@30cm

RANGE: GELWEAVE LUPIAE BRANCHED GRAFT		
SIZE	CATALOGUE NUMBER	USABLE LENGTH
22/10/10/8 x 10mm	734020CX4RMS	40cm + 40cm + 3@30cm
22/10/10/8 x 10mm	734022CX4RMS	40cm + 40cm + 3@30cm

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24/10/10/8 x10mm	734024CX4RMS	40cm + 40cm + 3@30cm
26/10/10/8 x 10mm	734026CX4RMS	40cm + 40cm + 3@30cm
28/10/10/8 x 10mm	734028CX4RMS	40cm + 40cm + 3@30cm
30/10/10/8 x 10mm	734030CX4RMS	40cm + 40cm + 3@30cm
32/10/10/8 x 10mm	734032CX4RMS	40cm + 40cm + 3@30cm
34/10/10/8 x 10mm	734034CX4RMS	40cm + 40cm + 3@30cm

RANGE: GELWEAVE SIENA™ COLLARED ANTE-FLO		
SIZE	CATALOGUE NUMBER	USABLE LENGTH
20/8mm	734520/8ET	45cm X 1 @ 30cm
22/8mm	734522/8ET	45cm X 1 @ 30cm
24/8mm	734524/8ET	45cm X 1 @ 30cm
26/8mm	734526/8ET	45cm X 1 @ 30cm
28/8mm	734528/8ET	45cm X 1 @ 30cm
30/8mm	734530/8ET	45cm X 1 @ 30cm
32/8mm	734532/8ET	45cm X 1 @ 30cm
34/8mm	734534/8ET	45cm X 1 @ 30cm
20/10mm	734520/10ET	45cm X 1 @ 30cm
22/10mm	734522/10ET	45cm X 1 @ 30cm
24/10mm	734524/10ET	45cm X 1 @ 30cm
26/10mm	734526/10ET	45cm X 1 @ 30cm
28/10mm	734528/10ET	45cm X 1 @ 30cm
30/10mm	734530/10ET	45cm X 1 @ 30cm
32/10mm	734532/10ET	45cm X 1 @ 30cm
34/10mm	734534/10ET	45cm X 1 @ 30cm

RANGE: GELWEAVE SIENA™ COLLARED 4 BRANCH PLEXUS		
SIZE	CATALOGUE NUMBER	USABLE LENGTH
20/10/8/8/8mm	73201088/8ET	30cm X 4 @ 15cm
22/10/8/8/8mm	73221088/8ET	30cm X 4 @ 15cm
24/10/8/8/8mm	73241088/8ET	30cm X 4 @ 15cm
26/10/8/8/8mm	73261088/8ET	30cm X 4 @ 15cm
28/10/8/8/8mm	73281088/8ET	30cm X 4 @ 15cm
30/10/8/8/8mm	73301088/8ET	30cm X 4 @ 15cm
32/10/8/8/8mm	73321088/8ET	30cm X 4 @ 15cm
34/10/8/8/8mm	73341088/8ET	30cm X 4 @ 15cm
20/10/8/8/10mm	73201088/10ET	30cm X 4 @ 15cm
22/10/8/8/10mm	73221088/10ET	30cm X 4 @ 15cm
24/10/8/8/10mm	73241088/10ET	30cm X 4 @ 15cm
26/10/8/8/10mm	73261088/10ET	30cm X 4 @ 15cm
28/10/8/8/10mm	73281088/10ET	30cm X 4 @ 15cm
30/10/8/8/10mm	73301088/10ET	30cm X 4 @ 15cm
32/10/8/8/10mm	73321088/10ET	30cm X 4 @ 15cm
34/10/8/8/10mm	73341088/10ET	30cm X 4 @ 15cm

RANGE: GELWEAVE SIENA™ COLLARED STRAIGHT WITH RADIOPAQUE MARKERS		
SIZE	CATALOGUE NUMBER	USABLE LENGTH
20mm	735020RM	50cm
22mm	735022RM	50cm
24mm	735024RM	50cm
26mm	735026RM	50cm
28mm	735028RM	50cm
30mm	735030RM	50cm
32mm	735032RM	50cm
34mm	735034RM	50cm

RANGE: GELWEAVE SIENA™ COLLARED ANTE-FLO WITH RADIOPAQUE MARKERS		
SIZE	CATALOGUE NUMBER	USABLE LENGTH
20mm	735020/8RM	50cm
22mm	735022/8RM	50cm
24mm	735024/8RM	50cm
26mm	735026/8RM	50cm

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28mm	735028/8RM	50cm
30mm	735030/8RM	50cm
32mm	735032/8RM	50cm
34mm	735034/8RM	50cm
20mm	735020/10RM	50cm
22mm	735022/10RM	50cm
24mm	735024/10RM	50cm
26mm	735026/10RM	50cm
28mm	735028/10RM	50cm
30mm	735030/10RM	50cm
32mm	735032/10RM	50cm
34mm	735034/10RM	50cm

RANGE: GELWEAVE SIENA™ COLLARED 4 BRANCH PLEXUS WITH RADIOPAQUE MARKERS		
SIZE	CATALOGUE NUMBER	USABLE LENGTH
20mm	73201088/8RM	50cm
22mm	73221088/8RM	50cm
24mm	73241088/8RM	50cm
26mm	73261088/8RM	50cm
28mm	73281088/8RM	50cm
30mm	73301088/8RM	50cm
32mm	73321088/8RM	50cm
34mm	73341088/8RM	50cm
20mm	73201088/10RM	50cm
22mm	73221088/10RM	50cm
24mm	73241088/10RM	50cm
26mm	73261088/10RM	50cm
28mm	73281088/10RM	50cm
30mm	73301088/10RM	50cm
32mm	73321088/10RM	50cm
34mm	73341088/10RM	50cm

RANGE: GELWEAVE VALSALVA		
SIZE	CATALOGUE NUMBER	USABLE LENGTH
16mm	730016ADP	15cm
18mm	730018ADP	15cm
20mm	730020ADP	15cm
22mm	730022ADP	15cm
24 mm	730024ADP	15cm
26 mm	730026ADP	15cm
28 mm	730028ADP	15cm
30 mm	730030ADP	15cm
32 mm	730032ADP	15cm
34 mm	730034ADP	15cm

RANGE: GELWEAVE VALSALVA (VS115)		
SIZE	CATALOGUE NUMBER	USABLE LENGTH
24 mm	730024ADPS	15cm
26 mm	730026ADPS	15cm
28 mm	730028ADPS	15cm
30 mm	730030ADPS	15cm
32 mm	730032ADPS	15cm
34 mm	730034ADPS	15cm

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RANGE: GELWEAVE VALSALVA WITH SHORTER SKIRT		
SIZE	CATALOGUE NUMBER	USABLE LENGTH
24mm	730024ADP20	15cm
26mm	730026ADP22	15cm
28mm	30028ADP23	15cm
30mm	730030ADP24	15cm
32mm	730032ADP26	15cm
34mm	730034ADP28	15cm

RANGE: GELWEAVE VALSALVA WITH LONGER SKIRT		
SIZE	CATALOGUE NUMBER	USABLE LENGTH
24mm	730024ADP50	15cm
26mm	730026ADP50	15cm
28mm	730028ADP50	15cm
30mm	730030ADP50	15cm
32mm	730032ADP50	15cm
34mm	730034ADP50	15cm

RANGE: GELWEAVE VALSALVA WITH COLLAR		
SIZE	CATALOGUE NUMBER	USABLE LENGTH
16mm	730016ADPS5	15cm
18mm	730018ADPS5	15cm
20mm	730020ADPS5	15cm
22mm	730022ADPS5	15cm
24 mm	730024ADPS5	15 cm
26 mm	730026ADPS5	15 cm
28 mm	730028ADPS5	15 cm
30 mm	730030ADPS5	15 cm
32 mm	730032ADPS5	15 cm
34 mm	730034ADPS5	15 cm

RANGE: GELWEAVE VALSALVA ANTE-FLO		
SIZE	CATALOGUE NUMBER	USABLE LENGTH
24 x 8 mm	734024/8ADP	40cm + 1 @ 15cm
26 x 8 mm	734026/8ADP	40cm + 1 @ 15cm
28 x 8 mm	734028/8ADP	40cm + 1 @ 15cm
30 x 8 mm	734030/8ADP	40cm + 1 @ 15cm
32 x 8 mm	734032/8ADP	40cm + 1 @ 15cm
34 x 8 mm	734034/8ADP	40cm + 1 @ 15cm
24 x 10 mm	734024/10ADP	40cm + 1 @ 15cm
26 x 10 mm	734026/10ADP	40cm + 1 @ 15cm
28 x 10 mm	734028/10ADP	40cm + 1 @ 15cm
30 x 10 mm	734030/10ADP	40cm + 1 @ 15cm
32 x 10 mm	734032/10ADP	40cm + 1 @ 15cm
34 x 10 mm	734034/10ADP	40cm + 1 @ 15cm

RANGE: GELWEAVE VALSALVA ANTE-FLO WITH SHORTER SKIRT		
SIZE	CATALOGUE NUMBER	USABLE LENGTH
24 x 8 mm	734024/8ADP20	40cm + 1 @ 15cm
26 x 8 mm	734026/8ADP22	40cm + 1 @ 15cm
28 x 8 mm	734028/8ADP23	40cm + 1 @ 15cm
30 x 8 mm	734030/8ADP24	40cm + 1 @ 15cm
32 x 8 mm	734032/8ADP26	40cm + 1 @ 15cm
34 x 8 mm	734034/8ADP28	40cm + 1 @ 15cm
24 x 10 mm	734024/10ADP20	40cm + 1 @ 15cm
26 x 10 mm	734026/10ADP22	40cm + 1 @ 15cm
28 x 10 mm	734028/10ADP23	40cm + 1 @ 15cm
30 x 10 mm	734030/10ADP24	40cm + 1 @ 15cm
32 x 10 mm	734032/10ADP26	40cm + 1 @ 15cm
34 x 10 mm	734034/10ADP28	40cm + 1 @ 15cm

EC Certificate - Full Quality Assurance System

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

No.**CE 00422****Issued To:**

**Vascutek Limited
a Terumo Company
Newmains Avenue
Inchinnan
Renfrewshire
Scotland
PA4 9RR
United Kingdom**

In respect of:

The design, development and manufacture of Sealed and Unsealed, Woven and Knitted Polyester, PTFE, Stented Nitinol Vascular Prostheses and Single Use Vascular Instruments.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **1994-12-21**

Date: **2020-04-23**

Expiry Date: **2023-03-02**

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Page 1 of 3

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 00422

Issued To:

**Vascutek Limited
a Terumo Company
Newmains Avenue
Inchinnan
Renfrewshire
Scotland
PA4 9RR
United Kingdom**

Number	Device Name	Intended purpose per IFU
Class III		
---	Gelseal Vascular Prostheses and Gelsoft Vascular Prostheses	See CE 00437
---	Extra Anatomical Knitted Vascular Prostheses	See CE 00513
---	Gelweave Vascular Prostheses with and without Radiopaque Markers	See CE 00514
---	Fluoropassiv Vascular Prostheses Fluoropassiv ER Vascular Prostheses Thin Wall Fluoropassiv Vascular Prostheses Thin Wall Fluoropassiv ER Vascular Prostheses	See CE 00875
---	Gelsoft Plus Vascular Prostheses	See CE 00876
---	Twillweave Woven Vascular Prostheses	See CE 01230
---	Cardiovascular Fabrics	See CE 01278
---	Expanded PTFE Sealed Vascular Grafts	See CE 52464
---	Anaconda™ AAA Stent Graft System	See CE 560098
---	Thoraflex Hybrid	See CE 589235

First Issued: **1994-12-21**

Date: **2020-04-23**

Expiry Date: **2023-03-02**

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Page 2 of 3

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 00422

Issued To:

**Vascutek Limited
a Terumo Company
Newmains Avenue
Inchinnan
Renfrewshire
Scotland
PA4 9RR
United Kingdom**

Number	Device Name	Intended purpose per IFU
Class IIb		
35281	Maxiflo Vascular Grafts	Maxiflo™ Vascular Prostheses, are indicated for the creation of subcutaneous arteriovenous conduits for blood access, bypass or reconstruction of occluded or diseased arterial blood vessels. MAXIFLO™ Vascular Prostheses are intended for systemic vascular repair (excluding the Central Circulatory System). This intended use includes the creation of subcutaneous arteriovenous conduits for blood access, bypass or reconstruction of occluded or diseased arterial blood vessels.
Class IIa		
MD0104	Graft Sizer	---

First Issued: **1994-12-21**Date: **2020-04-23**Expiry Date: **2023-03-02**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

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EC Certificate - Full Quality Assurance System

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

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 00422**
 Date: **2020-04-23**
 Issued To: **Vascutek Limited
 a Terumo Company
 Newmains Avenue
 Inchinnan
 Renfrewshire
 Scotland
 PA4 9RR
 United Kingdom**

Subcontractor:

Service(s) supplied

Collagen Solutions (UK) Ltd
 3 Robroyston Oval
 Nova Business Park
 Glasgow
 G33 1AP
 United Kingdom

Other Critical Processes

Gelita USA, Inc.
 2445 Port Neal Industrial Road
 Sergeant Bluff
 IA
 51054
 USA

Animal Tissues / Derivatives

Lake Region Medical
 340 Lake Hazeltine Drive
 Chaska
 Minnesota 55318
 USA

**Design
 Manufacture**

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EC Certificate - Full Quality Assurance System

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

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 00422**
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 Issued To: **Vascutek Limited
 a Terumo Company
 Newmains Avenue
 Inchinnan
 Renfrewshire
 Scotland
 PA4 9RR
 United Kingdom**

Subcontractor:	Service(s) supplied
Rousselot Isle sur la Sorgue SAS 253 Chemin Moulin Premier 84800 L'Isle-sur-la-Sorgue France	Animal Tissues / Derivatives
Synergy Health Sterilisation UK Ltd Brunel Close Drayton Fields Industrial Estate Daventry NN11 8RB United Kingdom	Radiation (Gamma Sterilization)
Terumo Europe N.V. Interleuvenlaan 40 3001 Leuven Belgium	EU Representative
Terumo Vietnam Co., Ltd. Lot 44-B-C Quang Minh Industrial Zone Me Linh District, Hanoi City Vietnam	Manufacture

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EC Certificate - Full Quality Assurance System

Certificate History

Certificate No: **CE 00422**
Date: **2020-04-23**
Issued To: **Vascutek Limited
a Terumo Company
Newmains Avenue
Inchinnan
Renfrewshire
Scotland
PA4 9RR
United Kingdom**

Date	Reference Number	Action
21 December 1994		First Issue.
19 May 1995		Griffith Micro Science Limited added to the sub-contractor list.
1 February 1996		Tissue Patches added to the scope.
13 September 1996		Isotron PLC (Bedford) added to the sub-contractor list.
21 September 1999		PTFE Vascular Protheses added to the scope and certificate renewal.
12 January 2001		Stented Vascular Protheses added to the scope.
03 March 2003		Nitinol Vascular Protheses added to the scope.

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

EC Certificate - Full Quality Assurance System

Certificate History

Certificate No: **CE 00422**
Date: **2020-04-23**
Issued To: **Vascutek Limited
a Terumo Company
Newmains Avenue
Inchinnan
Renfrewshire
Scotland
PA4 9RR
United Kingdom**

Date	Reference Number	Action
28 September 2005		Removal of Tissue Patches from the scope, and sterilizer name change from Griffith Micro Science Ltd to IBA and re-formatted company address adding Scotland.
21 September 2006		Heart Valve Conduits added to the scope. Kohler Medical Ltd added as a sub-contract manufacturer and sterilizer.
29 June 2007		Acquisition of subcontractor Koehler Medical Ltd. Change of name from Koehler Medical Ltd to Vascutek Limited, a Terumo Company and update to list of significant subcontractors.
03 March 2008	7005772	Certificate renewal including change of subcontractor name from IBA to Sterigenics. Also change "Disposable" to "Single Use" consistent with current terminology.

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

EC Certificate - Full Quality Assurance System

Certificate History

Certificate No: **CE 00422**
Date: **2020-04-23**
Issued To: **Vascutek Limited
a Terumo Company
Newmains Avenue
Inchinnan
Renfrewshire
Scotland
PA4 9RR
United Kingdom**

Date	Reference Number	Action
15 July 2010	7546406	Addition of Terumo Vietnam Co., to the list of significant subcontractors.
25 April 2012	7794623	Update the name of Isotron, Ltd to Synergy Health Sterilisation UK Ltd.
27 February 2013	7905922	Certificate renewal.
27 August 2015	8405023	Removal of "Heart Valve Conduits" from the scope and the significant subcontractor Vascutek Ltd (Swillington, Leeds).
23 October 2017	8595440	Addition of animal substance subcontractors Tyson Fresh Meat Inc. and Gelita USA Inc.
02 March 2018	8891380	Certificate renewal and addition of Synergy Health Daventry as a subcontractor for sterilization.

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Date	Reference Number	Action
05 February 2019	7778835	Traceable to NB 0086. Administrative Subcontractor Service wording update for: Gelita USA Inc, Iowa 51054 from "Animal Substances" to "Animal Tissues / Derivatives". Sterigenics Derbyshire DE55 4NJ from "Sterilization" to "ETO Sterilization". Synergy Health Sterilisation UK Ltd, Daventry NN11 8RB from "Sterilization" to "Gamma Sterilization". Synergy Health Sterilisation UK Ltd, Bradford BD4 6SE from "Sterilization" to "Gamma Sterilization". Tyson Fresh Meat Inc, Nebraska 68731 from "Animal Substances" to "Animal Tissues / Derivatives".
Current	3141527	Addition of Collagen Solutions (UK) Ltd, Lake Region Medical, Rousselot Isle sur la Sorgue SAS, and Terumo Europe N.V. to the list of significant subcontractors. Removal of Sterigenics, Synergy Health Sterilisation UK Ltd (Bradford), and Tyson Fresh Meat from the list of significant subcontractors. Addition of product table.

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 This certificate was issued electronically and is bound by the conditions of the contract.

Certificat de Înregistrare

SISTEMUL DE MANAGEMENT AL CALITĂȚII - ISO 13485:2016

Se certifică prin prezenta că:

Vascutek Limited
Newmains Avenue
Inchinnan
PA4 9RR
Marea Britanie

Deține certificatul cu numărul:

MD 93897

și aplică un Sistem de Management al Calității care respectă cerințele standardului ISO 13485:2016 pentru următorul domeniu de aplicare:

Proiectarea și fabricarea protezelor vasculare sigilate și nesigilate, țesute, tricotate, cu stent și din PTFE și instrumente vasculare de unică folosință.
Servicii de sterilizare a dispozitivelor medicale în conformitate cu EN ISO 11135:2014.

Semnătură indescifrabilă

Pentru și în numele BSI:

Gary E Slack, Vicepreședinte General - Dispozitive medicale

Data înregistrării inițiale: 14.02.2005

Data ultimei revizii: 14.05.2020

Data intrării în vigoare: 14.05.2020

Data expirării: 25.12.2022

Pagina: 1 din 1



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Acest certificat a fost emis pe cale electronică și rămâne proprietatea BSI și este obligat să respecte condițiile contractuale. Un certificat electronic poate fi autentificat [online](https://www.bsigroup.com/ClientDirectory).
Copiile tipărite pot fi validate la www.bsigroup.com/ClientDirectory

Informații și date de contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel.: + 44 345 080 9000 BSI Assurance UK Limited, înregistrată în Anglia sub numărul 7805321 la 389 Chiswick High Road, Londra W4 4AL, UK. Membru al Grupului de companii BSI.

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