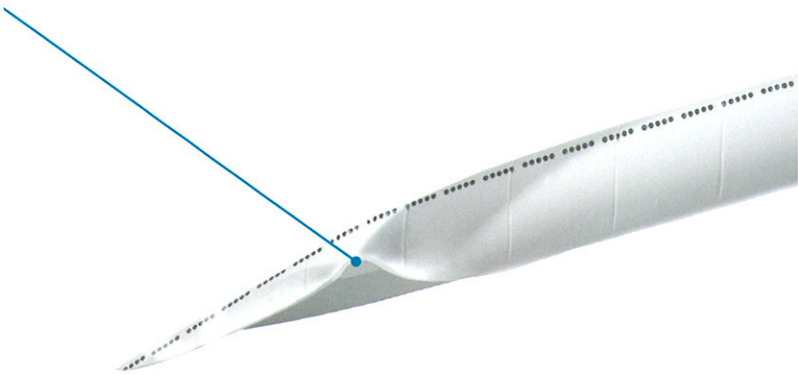
MAXIFLO™

DIE **kosteneffiziente** Lösung ihres **ePTFE**-Bedarfs



MAXIFLO™ Ultrathin

- Ultradünnwandiges ePTFE mit ausgezeichneten Handhabungseigenschaften[2]
- Verbesserte Knickresistenz für die Anpassung an das Gefäß[2]

MAXIFLO™ Wrap

- Normalwandiges ePTFE mit größerer Nahtrückhaltekraft[1]

MAXIFLO™- konisch zulaufende Produkte

- Konisch zulaufendes Design, speziell für den Gefäßzugang geschaffen
- Kurz konisches und gestuft konisches Design mit und ohne zentrale Polypropylenverstärkung erhältlich

MAXIFLO™ mit **Unity**™-Konstruktion

- Eine einzigartige PTFE-Verstärkung kann in die Anastomose integriert werden, wodurch ein *„Anastomose-Schutzsystem“* geschaffen wird[1]

MAXIFLO™ Ultrathin

Ultradünne Wand (0,35 mm)
Unbeschichtetes PTFE

Länge	Durchmesser	Keine Verstärkung	Verstärkung unity™ -Konstruktion	Verstärkung Voll-PTFE
	5 mm	T1005	T1005E	T1005P
	6 mm	T1006	T1006E	T1006P
10 cm	7 mm	T1007	T1007E	T1007P
	8 mm	T1008	T1008E	T1008P
	10 mm	T1010	T1010E	T1010P
	5 mm	T2005	T2005E	T2005P
	6 mm	T2006	T2006E	T2006P
20 cm	7 mm	T2007	T2007E	T2007P
	8 mm	T2008	T2008E	T2008P
	10 mm	T2010	T2010E	T2010P
	5 mm	T3005	T3005E	T3005P
	6 mm	T3006	T3006E	T3006P
30 cm	7 mm	T3007	T3007E	T3007P
	8 mm	T3008	T3008E	T3008P
	10 mm	T3010	T3010E	T3010P
	5 mm	T4005	T4005E	T4005P
	6 mm	T4006	T4006E	T4006P
40 cm	7 mm	T4007	T4007E	T4007P
	8 mm	T4008	T4008E	T4008P
	10 mm	T4010	T4010E	T4010P
	5 mm	T5005	T5005E	T5005P
	6 mm	T5006	T5006E	T5006P
50 cm	7 mm	T5007	T5007E	T5007P
	8 mm	T5008	T5008E	T5008P
	10 mm	T5010	T5010E	T5010P
	5 mm	T6005	T6005E	T6005P
	6 mm	T6006	T6006E	T6006P
60 cm	7 mm	T6007	T6007E	T6007P
	8 mm	T6008	T6008E	T6008P
	10 mm	T6010	T6010E	T6010P
	5 mm	T7005	T7005E	T7005P
	6 mm	T7006	T7006E	T7006P
70 cm	7 mm	T7007	T7007E	T7007P
	8 mm	T7008	T7008E	T7008P
	10 mm	T7010	T7010E	T7010P
	5 mm	T8005	T8005E	T8005P
	6 mm	T8006	T8006E	T8006P
80 cm	7 mm	T8007	T8007E	T8007P
	8 mm	T8008	T8008E	T8008P
	10 mm	T8010	T8010E	T8010P

MAXIFLO™ Wrap

Standardwand (0,47 mm)
Unbeschichtetes PTFE

Länge	Durchmesser	Keine Verstärkung	Verstärkung unity™ -Konstruktion	Verstärkung Voll-PTFE
	5 mm	S1005	S1005E	S1005P
	6 mm	S1006	S1006E	S1006P
10 cm	7 mm	S1007	S1007E	S1007P
	8 mm	S1008	S1008E	S1008P
	10 mm	S1010	S1010E	S1010P
	5 mm	S2005	S2005E	S2005P
	6 mm	S2006	S2006E	S2006P
20 cm	7 mm	S2007	S2007E	S2007P
	8 mm	S2008	S2008E	S2008P
	10 mm	S2010	S2010E	S2010P
	5 mm	S3005	S3005E	S3005P
	6 mm	S3006	S3006E	S3006P
30 cm	7 mm	S3007	S3007E	S3007P
	8 mm	S3008	S3008E	S3008P
	10 mm	S3010	S3010E	S3010P
	5 mm	S4005	S4005E	S4005P
	6 mm	S4006	S4006E	S4006P
40 cm	7 mm	S4007	S4007E	S4007P
	8 mm	S4008	S4008E	S4008P
	10 mm	S4010	S4010E	S4010P
	5 mm	S5005	S5005E	S5005P
	6 mm	S5006	S5006E	S5006P
50 cm	7 mm	S5007	S5007E	S5007P
	8 mm	S5008	S5008E	S5008P
	10 mm	S5010	S5010E	S5010P
	5 mm	S6005	S6005E	S6005P
	6 mm	S6006	S6006E	S6006P
60 cm	7 mm	S6007	S6007E	S6007P
	8 mm	S6008	S6008E	S6008P
	10 mm	S6010	S6010E	S6010P
	5 mm	S7005	S7005E	S7005P
	6 mm	S7006	S7006E	S7006P
70 cm	7 mm	S7007	S7007E	S7007P
	8 mm	S7008	S7008E	S7008P
	10 mm	S7010	S7010E	S7010P
	5 mm	S8005	S8005E	S8005P
	6 mm	S8006	S8006E	S8006P
80 cm	7 mm	S8007	S8007E	S8007P
	8 mm	S8008	S8008E	S8008P
	10 mm	S8010	S8010E	S8010P

MAXIFLO™ Wrap

Standardwand (0,47 mm)

zentrale PTFE -Verstärkung

Länge	Durchmesser	Artikelnummer
	6 mm	S4006CP
40 cm	7 mm	S4007CP
	8 mm	S4008CP
	6 mm	S5006CP
50 cm	7 mm	S5007CP
	8 mm	S5008CP

MAXIFLO™ Wrap

Standardwand (0,47 mm)

endständige PTFE Verstärkung

Länge	Durchmesser	Artikelnummer
50 cm	6 mm	S5006EP

MAXIFLO™

Konisch zulaufend
Arteriell (0,59 mm)*
Venös (0,36 mm)*

Gestuft konisch

Länge	Durchmesser	Artikelnummer
20 cm	4 - 6 mm	W20ST0406
20 cm	4 - 7 mm	W20ST0407
25 cm	4 - 6 mm	W25ST0406
25 cm	4 - 7 mm	W25ST0407
30 cm	4 - 6 mm	W30ST0406
30 cm	4 - 7 mm	W30ST0407
35 cm	4 - 6 mm	W35ST0406
35 cm	4 - 7 mm	W35ST0407
35 cm	5 - 8 mm	W35ST0508
40 cm	4 - 6 mm	W40ST0406
40 cm	4 - 7 mm	W40ST0407
40 cm	5 - 8 mm	W40ST0508
45 cm	4 - 6 mm	W45ST0406
45 cm	4 - 7 mm	W45ST0407
45 cm	5 - 8 mm	W45ST0508
50 cm	4 - 6 mm	W50ST0406
50 cm	4 - 7 mm	W50ST0407
50 cm	5 - 8 mm	W50ST0508

Gestuft konisch zentrale Verstärkung

Länge	Durchmesser	Artikelnummer
40 cm	4 - 7 mm	W40ST0407CR
45 cm	4 - 7 mm	W45ST0407CR
45 cm	5 - 8 mm	W45ST0508CR
50 cm	4 - 7 mm	W50ST0407CR

Kurz konisch

Länge	Durchmesser	Artikelnummer
30 cm	4 - 7 mm	W30T0407
40 cm	4 - 6 mm	W40T0406
40 cm	4 - 7 mm	W40T0407
45 cm	4 - 6 mm	W45T0406
45 cm	4 - 7 mm	W45T0407
50 cm	4 - 7 mm	W50T0407

Kurz konisch zentrale Verstärkung

Länge	Durchmesser	Artikelnummer
40 cm	4 - 6 mm	W40T0406CR
40 cm	4 - 7 mm	W40T0407CR
45 cm	4 - 7 mm	W45T0407CR

** Daten stammen von einem 4 - 7 Produkt*

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):

Albert Roossien, Regulatory Lead

First Issued: **1994-12-21** Date: **2019-02-05** Expiry Date: **2023-03-02**

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By Royal Charter

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:	**2019-02-05**
Issued To:	**Vascutek Limited** **a Terumo Company** **Newmains Avenue** **Inchinnan** **Renfrewshire** **Scotland** **PA4 9RR** **United Kingdom**

Subcontractor:	**Service(s) supplied**
Gelita USA, Inc. 2445 Port Neal Industrial Road Sergeant Bluff Iowa 51054 USA	**Animal Tissues / Derivatives**
Sterigenics Cotes Park Industrial Estate Somercotes, Alfreton Derbyshire, DE55 4NJ United Kingdom	**ETO Sterilization**
Synergy Health Sterilisation UK Ltd (Synergy Health – AST – Bradford) Roysdale Way Euroway Industrial Estate Bradford BD4 6SE United Kingdom	**Gamma Sterilization**

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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:	**2019-02-05**
Issued To:	**Vascutek Limited** **a Terumo Company** **Newmains Avenue** **Inchinnan** **Renfrewshire** **Scotland** **PA4 9RR** **United Kingdom**

Subcontractor:	**Service(s) supplied**
Synergy Health Sterilisation UK Ltd Brunel Close Drayton Fields Industrial Estate Daventry NN11 8RB United Kingdom	**Gamma Sterilization**
Terumo Vietnam Co., Ltd. Lot 44-B-C Quang Minh Industrial Zone Me Linh District, Hanoi City Vietnam	**Manufacture**
Tyson Fresh Meat Inc. 1131 Dakota Avenue Dakota City Nebraska 68731 USA	**Animal Tissues / Derivatives**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 00422**
Date: **2019-02-05**
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 Prostheses added to the scope.

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 00422**

Date: **2019-02-05**

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.

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 00422**

Date: **2019-02-05**

Issued To: **Vascutek Limited**
a Terumo Company
Newmains Avenue
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PA4 9RR
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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.

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 00422**

Date: **2019-02-05**

Issued To: **Vascutek Limited**
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Newmains Avenue
Inchinnan
Renfrewshire
Scotland
PA4 9RR
United Kingdom

Date	Reference Number	Action
Current	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".

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Vascutek Limited
Newmains Avenue
Inchinnan
PA4 9RR
United Kingdom

Holds Certificate Number: **MD 93897**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

The design and manufacture of sealed and unsealed, woven, knitted, stented and PTFE vascular prostheses and disposable vascular instruments.
Contract sterilization of medical devices in accordance with EN ISO 11135:2014.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2005-02-14
Latest Revision Date: 2020-05-14

Effective Date: 2020-05-14
Expiry Date: 2022-12-25

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