

# EC Design-Examination Certificate

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

**No.** **CE 01278**  
**Issued To:** **Vascutek Limited**  
**a Terumo Company**  
**Newmains Avenue**  
**Inchinnan**  
**Renfrewshire**  
**Scotland**  
**PA4 9RR**  
**United Kingdom**

In respect of:

**Cardiovascular fabrics**

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC Annex II Section 4 and Regulation 722/2012. The design conforms to the requirements of this directive and regulation. For marketing of these products an additional Annex II excluding 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: **1996-04-10**

Date: **2020-05-05**

Expiry Date: **2024-05-26**

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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 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.

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### Gelsoft Cardiovascular Fabric Patches

Catalogue number	Device name	Model, type	Intended purpose per IFU	Classification
960501S	Gelsoft Cardiovascular Fabric Patches	5 x 1 cm	Vascular or cardiovascular repair. The soft handling of the Gelsoft Patch makes it ideal for peripheral use.	Class III Implant
960501		5 x 1.5 cm		Class III Implant
960603		6 x 3 cm		Class III Implant
960701S		7 x 1 cm		Class III Implant
960701		7 x 1.5 cm		Class III Implant
960804		8 x 4 cm		Class III Implant
961001S		10 x 1 cm		Class III Implant
961001		10 x 1.5 cm		Class III Implant
961204		12 x 4 cm		Class III Implant
961208		12 x 8 cm		Class III Implant

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### Gelseal Cardiovascular Fabric Patches

Catalogue number	Device name	Model, type	Intended purpose per IFU	Classification
950804	Gelseal Cardiovascular Fabric Patches	8 x 4 cm	Vascular or cardiovascular repair. Due to its particularly high strength Gelseal Patches are especially suitable for thoracic use.	Class III Implant
951010		10 x 10 cm		Class III Implant
951020		10 x 20 cm		Class III Implant
951204		12 x 4 cm		Class III Implant
951208		12 x 8 cm		Class III Implant
951220		12 x 20 cm		Class III Implant

### Thin Wall Carotid Patch (Tapered)

Catalogue number	Device name	Model, type	Intended purpose per IFU	Classification
920675T	Thin Wall Carotid Patch (Tapered)	6 mm x 75 mm	Vascular or cardiovascular repair. The Thin Wall fabric is designed for Patch closure after endarterectomy, particularly of the carotid arteries.	Class III Implant
920875T		8 mm x 75 mm		Class III Implant
921050T		10 mm x 50 mm		Class III Implant
921075T		10 mm x 75 mm		Class III Implant
921010T		10 mm x 100 mm		Class III Implant
921550T		15 mm x 50 mm		Class III Implant
921575T		15 mm x 75 mm		Class III Implant
922512T		25 mm x 120 mm		Class III Implant
921015T		10 mm x 150 mm		Class III Implant

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Thin Wall Carotid Patch Tapered Without Black Line, Germany

Catalogue number	Device name	Model, type	Intended purpose per IFU	Classification
920675TS	Thin Wall Carotid Patch Tapered Without Black Line, Germany	6 mm x 75 mm	Vascular or cardiovascular repair. The Thin Wall fabric is designed for Patch closure after endarterectomy, particularly of the carotid arteries.	Class III Implant

Fluoropassiv Thin Wall Carotid Patch

Catalogue number	Device name	Model, type	Intended purpose per IFU	Classification
920675F	Thin Wall Carotid Patch	6 mm x 75 mm	The Thin Wall fabric is designed for patch closure after endarterectomy, particularly of the carotid arteries.	Class III Implant
920875F		8 mm x 75 mm		Class III Implant
921010F		10 mm x 100 mm		Class III Implant
921050F		10 mm x 50 mm		Class III Implant
921075F		10 mm x 75 mm		Class III Implant
921550F		15 mm x 50 mm		Class III Implant
921575F		15 mm x 75 mm		Class III Implant
922512F		25 mm x 120 mm		Class III Implant

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### Fluoropassiv Thin Wall Carotid Patch (Tapered)

Catalogue number	Device name	Model, type	Intended purpose per IFU	Classification
920611FT	Thin Wall Carotid Patch (Tapered)	6 mm x 110 mm	The Thin Wall fabric is designed for patch closure after endarterectomy, particularly of the carotid arteries.	Class III Implant
920675FT		6 mm x 75 mm		Class III Implant
920875FT		8 mm x 75 mm		Class III Implant
921010FT		10 mm x 100 mm		Class III Implant
921015FT		10 mm x 150 mm		Class III Implant
921050FT		10 mm x 50 mm		Class III Implant
921075FT		10 mm x 75 mm		Class III Implant
921550FT		15 mm x 50 mm		Class III Implant
921575FT		15 mm x 75 mm		Class III Implant
922512FT		25 mm x 120 mm		Class III Implant

Sealed product intended for use with or without a Heparin and / or Rifampicin dip

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## Certificate History

Date	Reference Number	Action
10 April 1996	MD 000128	First Issue.
02 April 1997	MD 000128	Change of company name to Sulzer Vascutek Ltd VP 1200K plus cardiovascular patch deleted from scope.
10 April 2001	MD 000128	5 yearly renewal.
03 July 2001	EQ 10023766 EQ 10020927	Sealed product intended for use with or without Heparin and/or Rifampicin dip added to scope.
01 May 2003	EQ 10048172	Change of company name to Vascutek Limited Change of geographical origin of the gelatin to Australia.
30 September 2004	EQ 10055409	Addition of Animal Tissue Directive 2003/32/EEC.
28 February 2006	EQ 10078004	Certificate Renewal.
25 May 2010	10110569	5 year update to SER for bovine gelatin coating.

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Date	Reference Number	Action
11 April 2011	10121507	Certificate renewal and removal of Triaxial Cardiovascular Patch, VP1200K Cardiovascular Patch, Triaxial Plus Cardiovascular Patch, Gelseal Plus Cardiovascular Patch, Gelsoft Plus Cardiovascular Patch, Fluoropassiv Gelseal Plus Cardiovascular Patch, Fluoropassiv Gelsoft Plus Cardiovascular Patch from the certificate.
19 February 2016	10160178	Certificate renewal. Removal of references to Fluoropassiv Gelseal Cardiovascular Patch and Fluoropassiv Gelsoft Cardiovascular Patch. Included reference to Regulation (EU) 722/2012.
05 February 2019	7778835	Traceable to NB 0086.
13 November 2019	9648157	Addition of Gelita Inc as an alternate supplier of gelatin for Gelsoft, Gelseal, Thin Wall (Tapered) and Thin Wall (Tapered without Black Line) Cardiovascular Fabric Patches. Devices table reformatted.
Current	3152501	Certificate Renewal.

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