

Declaration of Conformity Record

Manufacturer's Name: Vascutek Ltd, a TERUMO Company**Manufacturer's Address:** Newmains Avenue, Inchinnan, Renfrewshire PA4 9RR Scotland**Product Family:** Cardiovascular Fabrics**Product Class:** Class III**Product Range:**
Gelsoft Cardiovascular Fabric Patches
Gelseal Cardiovascular Fabric Patches
Thin Wall Carotid Patch (Tapered)
Thin Wall Carotid Patch Tapered Without Black Line, Germany
Fluoropassiv Thin Wall Carotid Patch
Fluoropassiv Thin Wall Carotid Patch (Tapered)**Revision Number:** EUDOC-006-003

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.:** 19 **Dated:** 23/04/20**EC Design Dossier examination No.** CE01278**Issued by:** BSI Netherlands (NB No: 2797)* **First Issued On:** 10/04/96**Current Issue No:** 13 **Dated:** 05/05/20

*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:A handwritten signature in black ink, appearing to read "R Lally".**Date:**

08 JUN 2020

Name: Robert Lally**Global VP of Regulatory Affairs**

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RANGE: GELSOFT CARDIOVASCULAR FABRIC PATCHES	
CATALOGUE NUMBER	SIZE
960501S	5 x 1 cm
960501	5 x 1½ cm
960603	6 x 3 cm
960701S	7 x 1 cm
960701	7 x 1½ cm
960804	8 x 4 cm
961001S	10 x 1 cm
961001	10 x 1½ cm
961204	12 x 4 cm
961208	12 x 8 cm

RANGE: GELSEAL CARDIOVASCULAR FABRIC PATCHES	
CATALOGUE NUMBER	SIZE
950804	8 x 4 cm
951010	10 x 10 cm
951020	10 x 20 cm
951204	12 x 4 cm
951208	12 x 8 cm
951220	12 x 20 cm

RANGE: THIN WALL CAROTID PATCH (TAPERED)	
CATALOGUE NUMBER	SIZE
920675T	6 mm x 75 mm
920875T	8 mm x 75 mm
921050T	10 mm x 50 mm
921075T	10 mm x 75 mm
921010T	10 mm x 100 mm
921550T	15 mm x 50 mm
921575T	15 mm x 75 mm
922512T	25 mm x 120 mm
921015T	10 mm x 150 mm
920675TS	6mm x 75 mm

RANGE: THIN WALL CAROTID PATCH TAPERED WITHOUT BLACK LINE, GERMANY	
CATALOGUE NUMBER	SIZE
920675TS	6mm x 75 mm

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RANGE: FLUOROPASSIV THIN WALL CAROTID PATCH	
CATALOGUE NUMBER	SIZE
920675F	6 mm x 75 mm
920875F	8 mm x 75 mm
921050F	10 mm x 50 mm
921075F	10 mm x 75 mm
921010F	10 mm x 100 mm
921550F	15 mm x 50 mm
921575F	15 mm x 75 mm
922512F	25 mm x 120 mm

RANGE: FLUOROPASSIV THIN WALL CAROTID PATCH (TAPERED)	
CATALOGUE NUMBER	SIZE
920675FT	6 mm x 75 mm
920611FT	6 mm X 110mm
920875FT	8 mm x 75 mm
921015FT	10 mm x 150 mm
921050FT	10 mm x 50 mm
921075FT	10 mm x 75 mm
921010FT	10 mm x 100 mm
921550FT	15 mm x 50 mm
921575FT	15 mm x 75 mm
922512FT	25 mm x 120 mm