

# EC Design-Examination Certificate

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

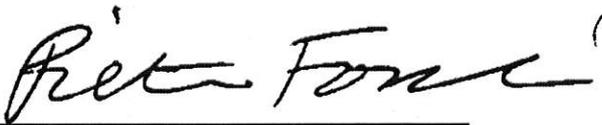
**No.** CE 00514  
**Issued To:** **Vasutek Limited**  
**a Terumo Company**  
**Newmains Avenue**  
**Inchinnan**  
**Renfrewshire**  
**Scotland**  
**PA4 9RR**  
**United Kingdom**

In respect of:

**Gelweave Vascular Prostheses with and without Radiopaque markers**

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 0086):



Pietro Foschi - Strategic Delivery Director

First Issued: **14 February 1995**

Date: **06 February 2015**

Expiry Date: **13 February 2020**

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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.

ES Dizaino-Tyrimo Sertifikatas  
Medicinos prietaisų direktyvas 93/42EEC, II priedas, 4 skyrius

Nr.: **CE 00437**  
Išduotas: **VASCUTEK LTD**  
**NEWMAINS AVENUE**  
**INCHINNAN**  
**RENFREWSHIRE**  
**Škotija**  
**PA4 9RR**  
**Jungtinė Karalystė**

dėl:  
**Gelweave kraujagyslių protezų su ir be Radiopaque žymeklio**

Remiantis mūsų tyrimais, atliktais vadovaujantis Tarybos direktyva 93/42/EEC, II priedas, 4 skyrius ir Reguliavima 722/2012 Didžiosios Britanijos Standartų Instituto notifikuotos institucijos.

Atsakingos už direktyvų vykdymą, vardu. (Notifikuotos institucijos Nr. 0086):

/Parašas/

Pietro Foschi, Globalus strategijos direktorius

Pirmą kartą išduota:

**1995 m. vasario mėn. 14 d** Data: **2015 m. vasario mėn. 06 d.** Galiojimo data: **2020 m. io mėn. 13 d.**

Puslapis: 1 iš 9

Patvirtinimo sąlygos

Šio sertifikato galiojimą sąlygoja Direktyvos kokybės sistema.

norint pakelti pasaulinis standartus



KOPIJA TIKRA  
IAUKR PEECS  
DIREKTORIUS