

**Company Information Form for Own-Brand/Private Label
Under the Medical Devices Directives.**

Please complete all relevant sections & sign in the space provided

COMPANY INFORMATION

Company Name		Viamed Ltd.			
Address		15, Station Road, Crosshills.			
City:	Keighley	Post Code:	BD207DT	Country:	W. Yorkshire
Phone:	+44 1535634542		Fax:	+44 1535 636	
Contact:	D.I. Lamb		Position:	Managing Director	
Alternative Contact:			Position:		
E-Mail:	DIL@viamed.co.uk		Web site:	www.viamed.co.uk	

OBL PRODUCT INFORMATION

Details of product(s) to be covered by OBL certificate	
Name of Original Equipment Supplier (OES)	
Address of OES	
OES Product Name(s) & Variants	
Is the product bought fully finished from the OES? (e.g. packaged, sterilized etc).	
What further processing (if any) do you carry out?	

DOCUMENTATION

Are the following documents available for review?	
OES & OBL Product Labels & Instructions For Use	
Copies of OES CE Certificates	
OBL Draft Declaration of Conformity	
OES Declaration of Conformity (Signed)	
Vigilance, PMS & Recall Procedures (if OBL is responsible)	
Contract / Agreement between OBL & OES	

OES / OBL AGREEMENT

Where does the Contract / Agreement define who is responsible for maintenance & availability of the following?	
	Page Reference
Description of product & variants	
Design Drawings	
Methods of manufacture	
Risk Management	
Evidence of compliance with Essential Requirements	
If sterile, details of protocol & validation	
Test reports, clinical data, etc	
Artwork for labels & instructions for use	
Access to documentation by BSI & Competent Authorities	
Documentation retention period	
Outline of arrangement to exchange PMS data	
Outline of arrangement & responsibility for vigilance reporting (including recalls & advisory notices)	
How each party & the Notified Body will be advised of any changes to the product or process	
OES & OBL approval signatures	

Signature:

Date:

Please return this Company Information Form to:-

BSI Product Services
 Maylands Avenue, Hemel Hempstead, Hertfordshire, HP2 4SQ
 Telephone: +44 (0) 1442 278607 Fax: +44 (0) 1442 278575