BSI
Product Services

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).	YES Not Sterile
What further processing (if any) do you carry out?	Basic Functional Test QA. Add Tracking nos. & Bar Codes

Product Services

DOCUMENTATION

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

OES / OBL AGREEMENT

Where does the Contract / Agreement define who is responsible for maintenance & availability of the following?	
	Page Reference
Description of product & variants	Section 3.0
Design Drawings	Section 4.0
Methods of manufacture	Section 4.0
Risk Management	Section 9.0
Evidence of compliance with Essential Requirements	Section 6.0
If sterile, details of protocol & validation	Not Applicable
Test reports, clinical data, etc	Section 6.0
Artwork for labels & instructions for use	Section 4.0
Access to documentation by BSI & Competent Authorities	Section 6.0
Documentation retention period	Section 2.0
Outline of arrangement to exchange PMS data	Section 10.0
Outline of arrangement & responsibility for vigilance reporting (including recalls & advisory notices)	Section 9.0
How each party & the Notified Body will be advised of any changes to the product or process	Section 10.0 Section 4.0
OES & OBL approval signatures	Section 11

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

BSI
Product Services

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	PULSE OXIMETRY
Name of Original Equipment Supplier (OES)	BLUEPOINT MEDICAL GmbH & Co. KG
Address of OES	AN der TRAVE 15 23923 SEMSDORF GERMANY
OES Product Name(s) & Variants	OXY TRUE
Is the product bought fully finished from the OES? (e.g. packaged, sterilized etc).	YES
What further processing (if any) do you carry out?	BASIC FUNCTIONAL TEST QA ADD. TRACKING NOS BAR CODE