Derek Lamb 230 Issues 3 ***Unread*** | Imported 25 Aug 12:36:43 | Out of Office: Future

Tom Thumb Viamed Product

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Documents in Date order Descending: Hover over thumbnail for more details

bsi.

EC Certificate - Full Quality Assurance System

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

No. CE 01389

Issued To: Viamed Limited
15 Station Road
Cross Hills
Keighley
West Yorkshire
BD20 7DT
United Kingdom

In respect of:

The design and manufacture of microstim nerve stimulators, oxygen hoods, gas respiratory adapters, gas respiratory valves and phototherapy light shields

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):

Frank Lee, EMEA Compliance & Risk Director

First Issued: 23 August 1996 Date: 06 September 2016 Expiry Date: 22 August 2021

...making excellence a habit.

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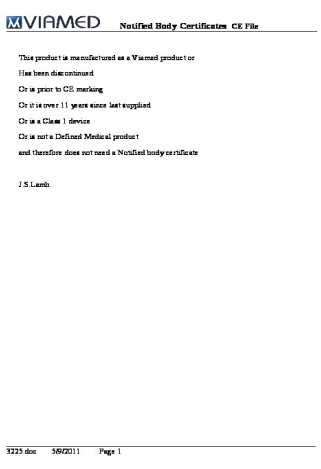

VIAMED Notified Body Certificates CE File

This product is manufactured as a Viamed product or

Has been discontinued

Or is prior to CE marking

Or it is over 11 years since last supplied

Or is a Class 1 device

Or is not a Defined Medical product

and therefore does not need a Notified body certificate

J S Lamb

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	E 4	EN ISO 14971:2001 Annex A	***2***	
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	BSI 0	Technical Agreements		
	BSI 1	Introduction to the device and any variants		
	BSI 2	Description of intended use		
	BSI 3	Product description		
	BSI 4	List of accessories		
	BSI 5	Location of responsibilities		
	BSI 6	Details of significant subcontractors as applicable		
	BSI 7	Solutions adopted to fulfil the Essential Requirements		
	BSI 8	Design input specification		
	BSI 9	Manufacturing process flow chart		
	BSI 10	Risk management document for the system		
	BSI 11.1	Detailed test results Device verification		
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	BSI 11.4	Evidence of Usability Human factors assessment		
	BSI 12	Details of Clinical investigations		
	BSI 13	post-market clinical follow-up plan		
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	BSI 16	Applicability of Machinery Directive 2006/42/EC		
	BSI 17	Classification rationale		
	BSI 18	Declaration of Conformity for the device		
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	BSI 20	Transportation and Storage test reports		
	SEPERATOR			