Test Certificate

regarding

Electrical Safety and Electromagnetic Compatibility Requirements

CEcert

CEcert GmbH, Alter Holzhafen 19, 23966 Wismar (Germany)

Test Laboratory

Certificate No.: 613.399.1

License Holder:	**Viamed Ltd.** **15 Station Road** **Cross Hills** **Keighley** **West Yorkshire BD20 7DT United Kingdom**	
Product identification::	Pulse oximeter equipment with Finger-Sensor	
Type/Model/Parameters:	**VM 2160 with Silicone Sensor**	
P/N:	0012160, 0012161, 0012162, 0012163, 0012164	
Test standards:	**IEC 60601-1:1988+A1:1991+A2:1995** **IEC 60601-1-2:2007** **ISO 9919:2005 applicable additional requirements**	
Classifications and Restrictions: **Electrical Safety**	Protection class: Applied part: Protection by enclosure:	Internally powered equipment Typ BF IPX2
EMC	Emission: Immunity:	Group 1 Class B not life supporting, to be used during patient transport outside health care facility
Environmental conditions:	Operation: Transport / Storage:	-20 to +50 °C, 15 – 95 %rH (no condensation), 600 – 1300 hPa -30 to +70 °C, 10 – 95 %rH (no condensation), 600 – 1500 hPa
Test reports:	408.123.2A Electrical Safety, 408.123.3 ISO 9919, 408.123.1B EMC, 408.123.4A SUV, 408.123.5 SEB IEC60601-1-8 413.399.1 KMF	
Test result:	**PASS**	

This test certificate is relevant exclusively to the item(s) submitted for testing.
Consider the test report specified in this certificate and the safety indications specified in the technical documentation to the product.

Head of test laboratory

DAkkS
Deutsche
Akkreditierungsstelle
D-PL-12049-01-01

Wismar, Friday, 25 October 2013

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Wismar, 02.04.2014

Viamed Ltd.
15 Station Road
Cross Hills
Keighley

West Yorkshire BD20 7DT United Kingdom

Mechanical strength tests (drop tests)

Product identification:	Pulse oximeter with finger sensor
Type/Model/Parameters:	VM 2160 with silicone sensor P/N: 0012160, 0012161, 0012162, 0012163, 0012164

The pulse oximeter equipment VM 2160 with the associated silicone sensors as listed above are tested according IEC 60601-1 and ISO 9919. These are the product standards for pulse oximeter equipment and include mechanical strength requirements as a sub-part of the electrical safety. Please be advised that the electrical safety is not restricted to electrical. It includes thermal requirements, fire hazards, mechanical requirements and all other functional safety requirements related to the safety of the equipment to be tested. The term electrical means other products than electrical equipment will not be certified.

The standard IEC 60601-1:1988+A1:1991+A2:1995 covers in clause 21 mechanical strength requirements. The pulse oximeter was tested according sub-clause 21.5 as a handheld equipment dropping from 1 m high onto hardwood surface, see test report 408.123.2A. With the silicone cover, the equipment including probe remains safe, no mechanical degradation and maintains full functionality as required. In addition ISO 9919:2005 requires additional tests regarding mechanical strength, see the attached excerpt of the test report 408.123.3.

In addition the equipment was tested as with mechanical shocks of 102 g and at least 30 min with mechanical vibration as described in b) of the test report excerpt.

CEcert is a independent test house accredited according national and European law, see link on homepage.

Bernd Schmidt
Head of Test Laboratory

Attachment: Excerpt of Test Report 408.123.3

CEcert GmbH; Alter Holzhafen 19a; D-23966 Wismar

Geschäftsführung
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Excerpt of Test Report 408.123.3

ISO 9919			
Clause	Requirement + Test	Result - Remark	Verdict
21.102	**Shock and vibration for transport**		P
	Pulse oximeter equipment or its parts, intended for use during patient transport outside a healthcare facility, shall have adequate mechanical strength when subjected to mechanical stress caused by normal use, pushing, impact, dropping, and rough handling.	see attachment # 7	P
	After the following tests, pulse oximeter equipment shall not cause a safety hazard and shall function normally.	functional test with functional test equipment, see attachment # 2	P
	a) Shock test in accordance with IEC 60068-2-27 (102g/ 6ms/ half sine, 3 shocks per direction per axis)	see attachment # 7	P
	b) Broad-band random vibration test in accordance with IEC 60068-2-64 (30 min per perpendicular axis - 10 Hz to 100 Hz: 5,0 (m/s2)2/Hz; - 100 Hz to 200 Hz: –7 db per octave; – 200 Hz to 2 000 Hz: 1,0 (m/s2)2/Hz)	see attachment # 7	P
	c) For mobile pulse oximeter equipment, free fall to IEC 60068-2-32, using Procedure 1 (height: 0,1 m; number of falls: one; direction: vertical, (normal operating position)	equipment tested in accordance to sub-clause d) and in accordance to general standard (1 m height free fall)	P
	d) For portable pulse oximeter equipment, free fall to IEC 60068-2-32, using Procedure 2 (height: 0,25 m; number of falls: one; direction: on each of the six surfaces.)	see attachment # 7	P
	For portable pulse oximeter equipment that is intended to be used with a carrying case, that case may be applied to the equipment during this test.		P
	Equipment tested and complying with the requirements in 21.102 in total or part, is considered to comply with the corresponding requirements of 21.101.		P

Possible test case verdicts:

- test case does not apply to the test object.....: N/A
- test object does meet the requirement.....: P (Pass)
- test object does not meet the requirement.....: F (Fail)

Testing:

Date of receipt of test item .....: 2008-05-05

Date (s) of performance of tests .....: 2008-05-05 – 2008-08-15