

Compliance Summary

regarding
Electrical Safety and Electromagnetic Compatibility and Environmental Conditions Requirements



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

Test Laboratory

No.: **616.255.3**

License Holder:	bluepoint MEDICAL GmbH & Co. KG An der Trave 15 23923 Selmsdorf, Germany	Viamed Ltd. 15 Station Road Cross Hills Keighley West Yorkshire BD20 7DT UK	
Product identification:	Pulse oximeter equipment with Silicone Finger-Sensor		
Type/Model/Parameters:	OxyTrue A	VM-2160	
P/N:	1020112001	0012160, 0012161, 0012162, 0012163, 0012164	
Applied standards:	IEC 60601-1: 2005 + CORR. 1 (2006) + CORR. 2 (2007) + AM1 (2012) or IEC 60601-1:2012 IEC 60601-1-2:2007 IEC 60601-1-8:2006 ISO 9919:2005		
Date of receipt test item(s):	2008-05-05 2013-10-18 2014-10-14 2014-06-04		
Dates tests performed:	2008-05-05 – 2013-10-18 – 2014-12-09 – 2014-06-04 –		
	2008-08-15 2013-10-25 2015-01-09 2014-06-06		
Sampling:	test of sample submitted		
Test report(s):	Electrical safety: 408.123.3, 413.399.1 414.280.2 EMC: 408.123.4A, 414.143.1 408.123.5,		
Test result:	PASS		

This test summary is relevant exclusively to the item(s) submitted for testing. This test summary is intended as cover sheet for the test report referenced. For details, see the test report specified in this summary and the safety instructions specified in the technical documentation to the product.



Wismar, Friday, 28 October 2016

Head of test laboratory

Dipl.-Ing. Bernd Schmidt

see 'Attachment 1' for more details

Classification:

Ratings:	Power supply:	internal battery 3 x 1.5 V, Type AA LR6 or 3 x NiMh 1.2 Volt, Typ AA HR6, 1200 mAh
Electrical safety:	Protection class:	Internally powered equipment, Type BF
	Protection by enclosure:	IP32 (with reusable probes)
	Clinical environment:	not intended to be used in presence of oxygen enriched environments or flammable aesthetic mixtures
	Installation and use:	hand-held
	Supply connection:	internally powered
	Max. altitude:	max. 4000 m
	Intended operator:	to be used by trained professionals
	Temperature of applied part:	< 41 °C
EMC:	Emission class:	Group 1, Class B
	Immunity class	not life supporting, to be used during patient transport outside health care facility
Environmental conditions:	Operation:	-20 to +50 °C, 15 – 95 %rH (no condensation), 600 – 1300 hPa
	Transport / Storage:	-30 to +70 °C, 10 – 95 %rH (no condensation), 600 – 1500 hPa
	Transportation:	equipment to be used during patient transport outside healthcare facility

End of Listing!