

# Test Certificate

regarding  
Electrical Safety and Electromagnetic Compatibility Requirements



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

**Test Laboratory**

**Certificate No.: 613.399.1**

|                                   |                                                                                                                                        |                                                                                       |
|-----------------------------------|----------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------|
| License Holder:                   | <b>Viamed Ltd.</b><br><b>15 Station Road</b><br><b>Cross Hills</b><br><b>Keighley</b><br><b>West Yorkshire BD20 7DT United Kingdom</b> |                                                                                       |
| Product identification::          | Pulse oximeter equipment with Finger-Sensor                                                                                            |                                                                                       |
| Type/Model/Parameters:            | <b>VM 2160 with Silicone Sensor</b>                                                                                                    |                                                                                       |
| P/N:                              | 0012160, 0012161, 0012162, 0012163, 0012164                                                                                            |                                                                                       |
| Test standards:                   | <b>IEC 60601-1:1988+A1:1991+A2:1995</b><br><b>IEC 60601-1-2:2007</b><br><b>ISO 9919:2005 applicable additional requirements</b>        |                                                                                       |
| Classifications and Restrictions: |                                                                                                                                        |                                                                                       |
| <b>Electrical Safety</b>          | Protection class:                                                                                                                      | Internally powered equipment                                                          |
|                                   | Applied part:                                                                                                                          | Typ BF                                                                                |
|                                   | Protection by enclosure:                                                                                                               | IPX2                                                                                  |
|                                   | Emission:                                                                                                                              | Group 1 Class B                                                                       |
| <b>EMC</b>                        | Immunity:                                                                                                                              | not life supporting, to be used during patient transport outside health care facility |
| <b>Environmental conditions:</b>  | 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                          |
| Test reports:                     | 408.123.2A Electrical Safety, 408.123.3 ISO 9919,<br>408.123.1B EMC, 408.123.4A SUV, 408.123.5 SEB IEC60601-1-8<br>413.399.1 KMF       |                                                                                       |
| Test result:                      | <b>PASS</b>                                                                                                                            |                                                                                       |

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.



Deutsche  
Akkreditierungsstelle  
D-PL-12049-01-01

**Head of test laboratory**

Dipl.-Ing. Bernd Schmidt

Wismar, Friday, 25 October 2013