

# Test Certificate

regarding  
Electrical Safety and Electromagnetic Compatibility Requirements



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

**Test Laboratory**

**Certificate No.: 608.029.4**

|                                   |                                                                                                                                                                                                                                                       |                                                                                              |            |           |                 |  |           |                                                                                              |
|-----------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------|------------|-----------|-----------------|--|-----------|----------------------------------------------------------------------------------------------|
| 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::          | <b>SpO2-Monitor with Finger-Sensor</b>                                                                                                                                                                                                                |                                                                                              |            |           |                 |  |           |                                                                                              |
| Type/Model/Parameters:            | <b>VM 2160-L with Finger Clip Sensor</b>                                                                                                                                                                                                              |                                                                                              |            |           |                 |  |           |                                                                                              |
| P/N:                              | <b>0012155, 0012156, 0012157, 0012158, 0012159</b>                                                                                                                                                                                                    |                                                                                              |            |           |                 |  |           |                                                                                              |
| Test standards:                   | <b>IEC 60601-1-2:2001 +A1:2004 (EN 60601-1-2:2001) and FDA<br/>Reviewer Guidance for Premarket Notification Submission /1993/<br/>with applicable additional requirements of ISO 9919:2005</b>                                                        |                                                                                              |            |           |                 |  |           |                                                                                              |
| Classifications and Restrictions: | <table border="0"> <tr> <td><b>EMC</b></td> <td>Emission:</td> <td>Group 1 Class B</td> </tr> <tr> <td></td> <td>Immunity:</td> <td>not life supporting, not to be used during patient<br/>transport outside health care facility</td> </tr> </table> |                                                                                              | <b>EMC</b> | Emission: | Group 1 Class B |  | Immunity: | not life supporting, not to be used during patient<br>transport outside health care facility |
| <b>EMC</b>                        | Emission:                                                                                                                                                                                                                                             | Group 1 Class B                                                                              |            |           |                 |  |           |                                                                                              |
|                                   | Immunity:                                                                                                                                                                                                                                             | not life supporting, not to be used during patient<br>transport outside health care facility |            |           |                 |  |           |                                                                                              |
| Test reports:                     | <b>408.189.1 EMC</b>                                                                                                                                                                                                                                  |                                                                                              |            |           |                 |  |           |                                                                                              |
| 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.



**Head of test laboratory**

Wismar, Wednesday, 22 July 2009

Dipl.-Ing. Bernd Schmidt