



宁波柯泰医疗器械有限公司  
NINGBO GREETMED MEDICAL INSTRUMENTS CO., LTD.

Certificate of Analysis

|   |  |                           |                             |                   |            |          |  |
|---|--|---------------------------|-----------------------------|-------------------|------------|----------|--|
| Item Name: Manual resuscitators   |  |                           |                             |                   |            |          |  |
| 批号 Lot No.  |  | 120956                    |                             | 规格 Specification  |            | CP681313 |  |
| 检验依据 Inspection standrad  |  | CP/QR 8.2.4-17            |                             | 数量 Quantity       |            | 300PCS   |  |
| 检验项目<br>Inspection item   | 标准值<br>Standard  | 抽样数量<br>Sampling quantity | 测试数值<br>Test data           | 单项判定 Single judge | 备注<br>Note |          |  |
| 外观 Appearance   | TP-001   | 5pcs                      | OK                          | 合格<br>Pass        |            |          |  |
| 复苏器病患阀接头尺寸<br>Patient valve<br>Connector dimension of resuscitator                                | 22OD锥度为(0-5.2)mm<br>the taper of 22OD shall be within (0-5.2) mm   | 5pcs                      | 2.5 2.7 2.4 2.8 2.5         | 合格<br>Pass        |            |          |  |
| 复苏器密封性<br>Leakage of Resuscitation  | 各部件连接良好, 按压气囊应充满硬度感, 无漏气声<br>Connection of parts is well, press the body is full of sense of hardness, not have sound of leakage       | 5pcs                      | OK                          | 合格<br>Pass        |            |          |  |
| 复苏器呼气阻抗<br>Expiratory resistance of resuscitation   | ≤5cmH <sub>2</sub> O (测试流量为50L/min)<br>Is not exceed 5cmH <sub>2</sub> O at 50L/min  | 5pcs                      | 2.1 2.2 2.2 2.1 2.3         | 合格<br>Pass        |            |          |  |
| 复苏器吸气阻抗<br>Inspiratory resistance of resuscitation  | ≤5cmH <sub>2</sub> O (测试流量为50L/min)<br>Is not exceed 5cmH <sub>2</sub> O at 50L/min  | 5pcs                      | 2.3 2.1 2.4 2.4 2.1         | 合格<br>Pass        |            |          |  |
| 复苏器压力阀限值<br>Pressure limitation of resuscitation  | 介于40cmH <sub>2</sub> O至60cmH <sub>2</sub> O之间(测试流量为60L/min)<br>Shall be Within 40cmH <sub>2</sub> O to 60cmH <sub>2</sub> O at 60L/min | 5pcs                      | 50.5 51.0 51.0 51.5<br>52.0 | 合格<br>Pass        |            |          |  |
| 面罩接头尺寸<br>Connector dimension of mask   | 22OD锥度范围为(0-5.2)mm<br>the taper of 22OD shall be within (0-5.2) mm   | 5pcs                      | 2.8 2.4 2.5 2.7 2.4         | 合格<br>Pass        |            |          |  |
| 面罩泄漏<br>Leakage of mask   | 无泄漏<br>No leakage  | 5pcs                      | OK                          | 合格<br>Pass        |            |          |  |
| 面罩剥离<br>Peel test of mask   | 用手对折挤压软垫四周, 软垫与上盖不可有分离现象<br>Folded around the air cushion with hands, The  | 5pcs                      | OK                          | 合格<br>Pass        |            |          |  |
| 面罩充/放气功能<br>Inflated and deflate function of mask   | 能正常充放气<br>Can be Inflated and deflate normal   | 5pcs                      | OK                          | 合格<br>Pass        |            |          |  |
| 面罩拉力<br>Tensile test of mask  | 充气阀门与气垫的分离力需大于5Kgf<br>the detached forces between valve and cushion shall  | 5pcs                      | 10.5 10.7 10.4 10.5<br>10.7 | 合格<br>Pass        |            |          |  |
|   | 气垫与上盖的分离力需大于3Kgf<br>the detached forces between cover and cushion shall  | 5pcs                      | 9.5 9.2 9.6 9.4<br>9.6      | 合格<br>Pass        |            |          |  |
| 氧气管泄漏<br>Leakage of oxygen tubing   | 保压150cmH <sub>2</sub> O, 5S无压降<br>No pressure drop under 150cmH <sub>2</sub> O for 5s  | 5pcs                      | OK                          | 合格<br>Pass        |            |          |  |
| 氧气管阻抗<br>Resistance of oxygen tubing  | 阻抗小于0.9kPa/m(测试流量为4L/min)<br>Reistance must be less than 0.9kPa/m at 4L/min  | 5pcs                      | 0.4 0.5 0.6 0.5 0.4         | 合格<br>Pass        |            |          |  |
| 氧气管折曲阻抗<br>Resistance to linking test of oxygen tubing  | 输出流量不得低于原输入流量的75%(原输入流量为10L/min)<br>the flow through the kinked tubing shall be not less   | 5pcs                      | OK                          | 合格<br>Pass        |            |          |  |
| 氧气管拉力<br>Tensile test of oxygen tubing  | 氧气管接头与氧气管身的分离力, 分离力需大于4.5kgf<br>the detached forces between connector and tubing shall be more than 4.5kgf                             | 5pcs                      | 9.4 9.3 9.2 9.5 9.3         | 合格<br>Pass        |            |          |  |
| 储气袋容量<br>capacity of reservoir bag  | 2000ML±200ML   | 5pcs                      | 2007 2012 2010 2018         | 合格<br>Pass        |            |          |  |
| 数量<br>Quantity  | 300 pcs  | N/A                       | OK                          | 合格<br>Pass        |            |          |  |
| 综合判定 Final judge: <input type="checkbox"/> 合格 qualified <input type="checkbox"/> 不合格 disqualified |  |                           |                             |                   |            |          |  |
| 检验<br>Inspected by  | Wuyi   | 审核<br>Review by           | Luqi                        | 批准<br>Approve by  |            |          |  |

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