



## Certificate of Conformance 合格证书

Date Released: 出货日期:	2021-10-12	Document Number: 文件编号:	DH-00003709
Product Name: 产品名称:	ECG CABLE	Customer Name: 客户名称:	VIAMED
Customer Part Number: 客户零件号:	14C-68660	Customer Part Revision: 客户零件号版本:	B
Customer Drawing Number: 客户图纸编号:	14C-68660	Customer Drawing Revision: 客户图纸版本:	B
Purchase Order No: 订购单号码:	PVM2037	Lot Number: 批号:	096696
Quantity: 数量:	2000PCS	Date Code: 生产日期代码:	2021-09-17

Note: All records must meet the requirements of Good Writing Practice OIQA-027

### Carlisle Medical Technologies (Dongguan) Co., Ltd.

No.2, Qiaolong Road, Xinhui Industrial Park Dengwu Village, Qiaotou Town, Dongguan City, Guangdong, PR China 523533

Carlisle Medical Technologies certifies the product being provided meets applicable specifications listed above having the test results and materials listed below and has been manufactured in accordance with ISO 13485:2016 Quality System requirements and FDA current Good Manufacturing Practices 21CFR Part 820.

Carlisle Medical Technologies 证明所提供的产品符合上面列出的适用规格，下面列出的测试结果和材料，并根据 ISO 13485: 2016 质量体系要求和 FDA 当前的 Good Manufacturing Practices 21CFR Part 820 进行制造。

NAME OF TEST 测试名称	SPECIFICATIONS OF TEST *OR* TEST PROCEDURE AND REVISION 测试*或*测试程序和修订的规范
Continuity 连续性测试	No open or no short.
Hi-pot 高压测试	1000VAC/0.25mA
Insulation resistance 绝缘电阻	100Mohm/DC500V
CABLE COMPONENTS 电缆组件	MATERIAL SPECIFICATIONS 材质规格
Cable	Material PU
Plug	ECG plug, nontoxic PVC 90+/-5 shore A
Block	Material PU 60+/-5 shore A
Housing of connector	Material PVC 90+/-5 shore A
Connector/snapper	Stainless steel
Certified by: 认证人:	<div style="display: flex; justify-content: space-between; align-items: center;"> <div>             Quality Representative Name 质量代表姓名         </div> <div>             Signature 签名         </div> <div>           2021.10.12            Date 日期         </div> </div>

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Form #: QMS-00000591  
QC#: QCN-00003110

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# Material Declaration of Compliance

## 材料声明

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No.2, Qiaolong Road, Xinhua Industrial Park Dengwu Village,  
Qiaotou Town, Dongguan City,  
Guangdong, PR China 523533

Carlisle Medical Technologies certifies the product identified above has been manufactured in accordance with the following requirements:

**Restriction of Hazardous Substances Directive European Union Regulation** [check those that apply]

☒ RoHS 2.0 Directive 2011/65/EU and its amendments (EU)2015/863

**Registration, Evaluation, Authorization, and Restriction of Chemicals** [check when it applies]

☐ REACH European Union Regulation (EC) 1907/2006

Carlisle Medical Technologies 证明上述产品符合以下要求

欧盟有害物质指令限制条例 [检查适用的项目]

☒ RoHS 2.0 指令 2011/65 / EU 及其修正指令(EU)2015/863

化学品的注册, 评估, 授权和限制[在适用时进行检查]

☐ REACH 欧盟法规 (EC) 1907/2006

Certified by:

认证人:

Quality Representative Name 质量代表姓名

Signature 签名

Date 日期

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