



Lloyd's Register  
LRQA

## EC CERTIFICATE – PRODUCTION QUALITY ASSURANCE SYSTEM

**In accordance with the requirements of the Medical Devices Directive 93/42/EEC and the Medical Devices Regulations 2002, UK Statutory Instrument 2002 No. 618**

This is to certify that the Quality Management System of:

**Prizm Medical Inc.  
1236 Doker Drive  
Modesto, California 95351, USA**


has been assessed against the requirements of Annex V of the Medical Devices Directive 93/42/EEC, and the Medical Devices Regulations 2002 and conforms to the requirements for the products shown on the attached schedule.

Approval is subject to the maintenance of the quality system in accordance with the requirements of the above Directive and Regulations.

Authorisation is hereby given to use the LRQA Notified Body Registration Number in accordance with the requirements of the specified Directives/Regulations in relation to the products as identified above.

This certificate forms part of the approval identified by certificate number UQA 0961678

Certificate No: 0961678/B  
Original Approval: September 23, 1999  
Current Certificate: August 1, 2014  
Certificate Expiry: July 31, 2019  
LRQA Notified Body Number 0088

  
Issued by: Lloyd's Register Quality Assurance Limited



## EC CERTIFICATE – PRODUCTION QUALITY ASSURANCE SYSTEM CERTIFICATE 0961678/B SCHEDULE

In accordance with the requirements of the Medical Devices  
Directive 93/42/EEC and the Medical Devices Regulations 2002, UK  
Statutory Instrument 2002 No. 618

**Prizm Medical Inc.  
1236 Doker Drive  
Modesto, California 95351, USA**

### **Class II Products**

**Micro-Z™ Wearable Pulsed Galvanic Electrical Stimulator Systems.  
Micro-Z™ Mini Wearable Pulsed Galvanic Electrical Stimulator Systems.  
Firefly (5000 Z System) Wearable Pulsed Galvanic Electrical Stimulator Systems.  
Electro-Mesh™ Electrodes: Glove, Sleeve, Sock, Bandage, Panels.  
Silver-Thera™ Electrodes: Stockings, Gloves, Stim Supports.**

#### **Electro-Mesh™ Electrodes:**

- Electro-Mesh™ Glove
- Electro-Mesh™ Sleeve
- Electro-Mesh™ Sock
- Electro-Mesh™ Bandage
- Electro Mesh™ Panels

#### **Silver-Thera™ Electrodes:**

- Silver-Thera™ Stocking
- Silver-Thera™ Gloves
- Stim-Supports

#### **Firefly Electrode:**

- Firefly 5000Z System Gel Pad Electrode.

Schedule Issue: Six  
Date of Schedule Issue: August 1, 2014  
LRQA Notified Body Number 0088



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