





CERTIFICATE OF COMPLIANCE

Certificate No.: Date of Issue:

C159520.01 8 February 2016

Applicant Name: Q-Core Medical Ltd.

Applicant Address 29 Yad Haruzim St., P.O.Box 8639 Netanya 4250529, Israel

Product SapphirePlus Infusion Pump

Model / Type Ref. Sapphire Infusion Pump, Sapphire Multi Therapy Infusion

Pump, Sapphire PCA Infusion Pump, Sapphire Epidural

Infusion Pump, Sapphire TPN Infusion Pump, SapphrieH100

Infusion Pump, SapphirePlus Infusion Pump

Rating 7.4Vdc, 1960mAh (from rechargeable Li-lon battery)

AC/DC Adapter/Battery charger: In: 100-240Vac, 50-60Hz, 0.18-0.6A;

Out: 10Vdc, 1.25A Max.

Classification Internally powered / Class II equipment

Transportable, Airborne, Transient operable

Tested to: IEC 60601-1-12:2014 (1st Ed.)

Medical electrical equipment - Part 1-12: Collateral standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical

services environment.

Test Results are detailed in the Test

Reports No. **\$159520.01**

Steli Loznen, M.Sc.

Signature:

Certification Dept.

This is to certify that the product specified herein has been tested & the test results were found to be compliant with the requirements noted above.

ITL091 Rev 3.1 21/05/13