



QPS Evaluation Services Inc
Testing, Certification and Field Evaluation Body
Accredited in Canada, the USA, and Internationally

LETTER OF ATTESTATION

CE Marking Assistance – Essential Health & Safety Requirements

Project Number: CE90146-1R1

Product Type/Model: LED Laryngoscope Handle, Models GS-MED-A-XX, GS-PEN-A-XX
LED Handle for Sigmoidoscope/Anoscope Illuminators, Model GS-LEI-A-HP
where XX may be either NA or EU or blank

Name/Address of Applicant: Orion Concepts Inc.
2-451 Enfield Road, Burlington, Ontario, L7T 2X5, Canada

Name/Address of Manufacturer: Orion Concepts Inc.
2-451 Enfield Road, Burlington, Ontario, L7T 2X5, Canada

Name/Address of Factory: Same as manufacturer

Ratings and other Parameters: Internally powered (3Vdc)

Related EU Directive(s): Medical Devices Directive 93/42/EEC

Applicable Test Standard(s): EN 60601-1:1990 - Medical Electrical Equipment Part 1: General Requirements for Safety - Incorporates Amendments A1: 1993, A11: 1993, A12: 1993, A2: 1995 and A13: 1996; Incorporates Corrigenda July 1994 and August 2005

IMPORTANT DECLARATIONS

- QPS Evaluation Services, Inc. attests to the results contained in EN test report CE90146-1R1 for the above products, indicating compliance with the above referenced standard(s).
- This attestation is based on evaluation of a sample of the above noted product to the safety requirements contained in the above referenced standards. This attestation does not imply an assessment to all the requirements of the "Related Directive" nor to the whole production of the product.
- It must be noted that in order to be eligible to bear the CE marking, the product may have to meet additional requirements contained in several applicable European Directives, which are not covered by QPS under this evaluation.
- The manufacturer of the product is responsible for ensuring that the product involved complies with all the applicable EU Directives, for issuing the required "Declaration of Conformity", and for applying the CE Marking on the product. The holder of this Letter of Attestation is authorized to use it for the purpose of supporting the "Declaration of Conformity".

THIS ATTESTATION LETTER DOES NOT AUTHORIZE ITS HOLDER TO USE THE QPS CERTIFICATION MARK ON THE SUBJECT PRODUCTS. THE USE OF THE NAME OF QPS EVALUATIONS SERVICES, OR ITS REGISTERED TRADEMARK IN ANY WAY IS NOT PERMITTED WITHOUT PRIOR WRITTEN CONSENT OF QPS.

This Attestation Letter is valid as long as the design and construction of the subject product model is the same as the tested sample, as described in the above referenced EN report.

Issued By: Scott Airdrie

Signature:

Date: February 12, 2016