Declaration of Conformity to the

Medical Device Directive 93/42 EEC

As amended up to and including the 2007/47/EC amendments

Products covered by this declaration are:
Quasar eLite

As the Manufacturer Brandon Medical Company Ltd hereby declares that the class I devices specified above conform to the above Directive as transposed in to national regulations and statutes of the United Kingdom, such compliance having been demonstrated via:

- A Design File compliant to Annex VII
- Compliance to the Essential Requirements as per Annex I
- Quality Assurance procedures meeting the requirements of BS EN ISO13485:2012 Certificate Number 544B issued by Intertek
- Compliance and testing in accordance with BS EN 60601-1 and BS EN 60601-1-2
- Application of the following standards BS EN 14971 and BS EN 60601-2-41
- GMDN Code 12282 "Operating light".

The CE marking of product being subject to the maintenance of a registration with a Competent Authority, which has been undertaken with the UK Competent Authority, The Medicines and Healthcare products Regulatory Agency of the United Kingdom, with reference number CA006837

Directive 93/42/EEC. The devices do not include animal or human tissue or blood products or derivatives thereof or products that would be considered to be medicinal substances or use Phthalates as defined in the Essential Requirements, nor constitute a machine or PPE.

This is to certify that the above statement is true and relates to product manufactured from this date.

Signed _____
For and on Behalf of Brandon Medical Co Ltd being a duly authorised officer of the company.

SAO Y BẢN CHÍNH
Ngày 29 tháng 10 năm 2020

Name Nigel Davill

Job Title Technical Director

Date 01 May 2014

GIÁM ĐỐC

M.S.D.N: 0303234198 - C.T.T.N.H.H
CÔNG TY TRÁCH NHIỆM HỮU HẠN TRANG THIẾT BỊ DỤNG CỤ Y KHOA TÂN MAI THÀNH
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