By Royal Charter

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. **CE 545451**

Issued To: **Michelson Diagnostics Ltd**
Ground Floor Eclipse House
Eclipse Park
Sittingbourne Road
Maidstone
Kent
ME14 3EN
United Kingdom

In respect of:

Design and manufacture of OCT topical imaging systems and associated equipment

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Albert Roossien, Regulatory Lead

First Issued: **2009-07-29** Date: **2019-02-13** Expiry Date: **2019-07-28**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.
This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780
BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.
A member of BSI Group of Companies.

EC Certificate - Full Quality Assurance System Certificate History

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Date	Reference Number	Action
29 July 2009	7304460	First Issue.
24 June 2014	8135227	Renewal of certificate and upgrade to Annex II using the same certificate number.
09 July 2015	8313239	Reissue due to address change.
Current	8892266	Traceable to NB 0086.

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