By Royal Charter

EC Certificate - Full Quality Assurance System

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

No. **CE 608515**

Issued To: **Visionsense Ltd.**
20 Hamagshimim Street
Petach-Tikva
49348
Israel

In respect of:

Design, manufacture and inspection of stereoscopic vision systems for invasive surgery, and for capturing and viewing fluorescent images for the visual assessment of blood flow

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 0086):

Pietro Foschi - Strategic Delivery Director

First Issued: **06 February 2014** Date: **23 February 2015** Expiry Date: **26 August 2018**

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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, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 845 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A member of BSI Group of Companies.

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

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 608515**
Date:	**23 February 2015**
Issued To:	**Visionsense Ltd.** **20 Hamagshimim Street** **Petach-Tikva** **49348** **Israel**

Subcontractor:	**Service(s) supplied**
Medes Limited 5 Beaumont Gate Shenley Hill Radlett Hertfordshire WD7 7AR United Kingdom	**EU Representative**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 608515**

Date: **23 February 2015**

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20 Hamagshimim Street
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Date	Reference Number	Action
06 February 2014	8082815	First issue, transfer from Intertek certificate number MED-0172-1
23 February 2015	8120704	Extension to scope, "stereoscopic vision system for capturing and viewing fluorescent images for the visual assessment of blood flow".

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