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By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2003

This is to certify that:

InfraScan, Inc.
3508 Market Street
Philadelphia
Pennsylvania
19104
USA

Holds Certificate No: **FM 533560**

and operates a Quality Management System which complies with the requirements of ISO 13485:2003 for the following scope:

Design, development, manufacture and distribution of brain hematoma detection devices.

For and on behalf of BSI:

VP Regulatory Affairs, BSI Group America Inc.

Originally registered: 06/11/2008 Effective Date: 05/07/2014 Expiry Date: 05/06/2017

CMDCAS Recognized Registrar

SCC Accredited CB-MS OCSM Accrédité CCN

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Certificate

Production Quality Assurance

No. CE 534424

Issued to:

InfraScan, Inc.
3508 Market Street
Philadelphia
Pennsylvania
19104
USA

In respect of:

Manufacture of brain hematoma detectors

on the basis of our examination under the requirements of Council Directive 93/42/EEC, Annex V, Section 3.2.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):

Gary Fenton, Global Assurance Director

First Issued: **23 Jun 2008** Date: **24 May 2013**

Expiration Date: **22 Jun 2018**

Conditions of Approval
Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive. 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.

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Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: +44 (0)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 the BSI Group of Companies.

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Certificate

List of Significant Subcontractors

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

Certificate No.	**CE 534424**
Date:	**24 May 2013**
Issued to:	**InfraScan, Inc.** **Philadelphia** **USA**

Subcontractor	**Service(s) supplied**
Inteprod LLC 970-200 Rittenhouse Road Eagleville Pennsylvania 19403 USA	Manufacture
Qarad, BVBA Cipalstraat 3 B-2440 Geel Belgium	EU Representative

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Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: +44 (0)845 080 9000

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Certificate

History of Quality Assurance Certificate

Certificate No: **CE 534424**

Date: **24 May 2013**

Issued to: **InfraScan, Inc.**
Philadelphia
USA

Date	Reference Number	Action
23 June 2008	7172389	First issue
07 February 2012	7792764	Addition of new significant subcontractor: Inteprod LLC, 970-200 Rittenhouse Road, Eagleville, PA 19403, USA for Manufacture. Removal of "Suite 215" from the certificate address.
24 May 2013	7944651	Certificate Renewal. Ximedica subcontractor deleted. Qarad, BVBA added as EU Representative.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 11, 2013

Hogan Lovells US LLP
% Steven B. Datlof, M.D., J.D.
Official Correspondent
InfraScan, Incorporated
1835 Market Street, 2 9th floor
Philadelphia, PA 19103

Re: K120949
Trade/Device Name: Infrascanner Model 2000
Regulation Number: 21 CFR 882.1935
Regulation Name: Near Infrared (NIR) Brain Hematoma Detector
Regulatory Class: Class II
Product Code: OPT
Dated: December 13, 2012
Received: December 13, 2012

Dear Dr. Datlof:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Deborah L. Falls

for Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K120949

Device Name: Infrascanner Model 2000

Indications for Use:

The Infrascanner is indicated for the detection of traumatic supratentorial hematomas of greater than 3.5 mL in volume that are less than 2.5 cm from the brain surface, as an adjunctive device to the clinical evaluation in the acute hospital setting of patients 18 years old or greater with suspected traumatic supratentorial intracranial hematoma. The device is indicated to assess patients for CT scans but should not serve as a substitute for these scans. The Infrascanner is indicated for use by Physicians, or under the direction of a physician, who has been trained in the use of the device.

Prescription Use X (21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Deborah Falls

(Division Sign Off)
Division of Neurological and Physical Medicine Devices (DNPMD)

510(k) Number K120949