



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):

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Gary Fenton, Global Assurance Director

First Issued: **23 Jun 2008**

Date: **24 May 2013**

Expiration Date: **22 Jun 2018**

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## 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.

...making excellence a habit.™



## List of Significant Subcontractors

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

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



## 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.