



EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

No. CE 609595
Issued To: **Intrinsyk Medical Devices**
15 Ermer Road #205
Salem
New Hampshire
03079
USA

In respect of:

The manufacture of Single-use Sterile Lancets and Single-use Sterile Safety Lancets

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

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

Gary Fenton, Global Assurance Director

First Issued: **02 June 2014**

Date: **02 June 2014**

Expiry Date: **01 June 2019**

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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.