



Certificate GB03/59951

The management system of

Radox Laboratories Ltd

Ardmore, Diamond Road, Crumlin,
Co Antrim, BT29 4QY, UK

has been assessed and certified as meeting the requirements of

ISO 13485:2003



For the following activities

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 29 March 2010 until 18 August 2012 and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 06 August 2012
Issue 7. Certified since 18 August 2003

This is a multi-site certification.
Additional site details are listed on the subsequent page.

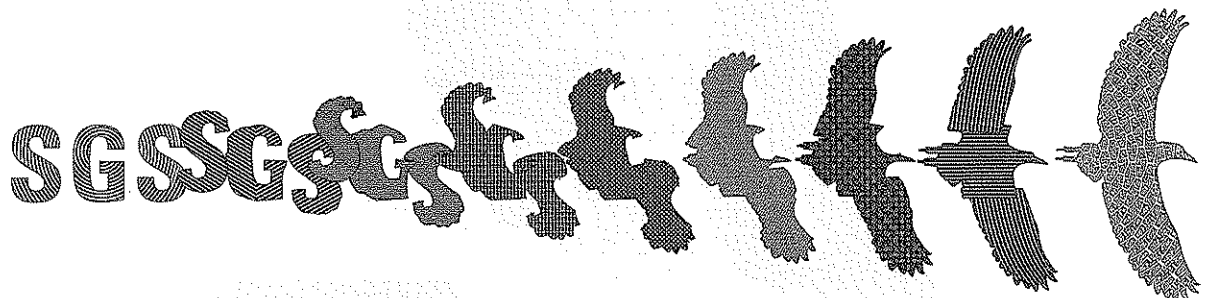
Authorised by

SGS United Kingdom Ltd Systems & Services Certification
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com



SGS 13485-2 1109 M2

Page 1 of 2



Radox Laboratories Ltd

ISO 13485:2003



Issue 7

Detailed scope

The design/development, manufacture, service and distribution of in-vitro diagnostic medical devices, in-vitro diagnostic test kits, in-vitro diagnostic reagents and in-vitro diagnostic analysers used in diagnosis and management of cancer, diagnosis of immune status, disease status and autoimmune status, and the identification of drugs of abuse, cardiac markers, protein metabolism, endocrine disorders, blood analytes, blood components, blood gases, coagulation, transmissible agents, sexually transmissible agents, fertility and for immunological typing and therapeutic drug monitoring.

Additional facilities

34 Diamond Road, Crumlin, Co Antrim, BT29 4QY, UK

36 Largy Road, Crumlin, Co Antrim, BT29 4RN, UK

44 Largy Road, Crumlin, Co Antrim, BT29 4RN, UK



005