



Certificate GB03/59951

The management system of

# Radox Laboratories Ltd

Ardmore, 55 Diamond Road, Crumlin, Co Antrim, BT29 4QY, UK



has been assessed and certified as meeting the requirements of

## ISO 13485:2003 EN ISO 13485:2012

For the following activities

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

This certificate is valid from 30 October 2015 until 18 August 2018  
and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 06 August 2018

Issue 15. Certified since 18 August 2003

This is a multi-site certification.

Additional site details are listed on the subsequent page.

Authorised by

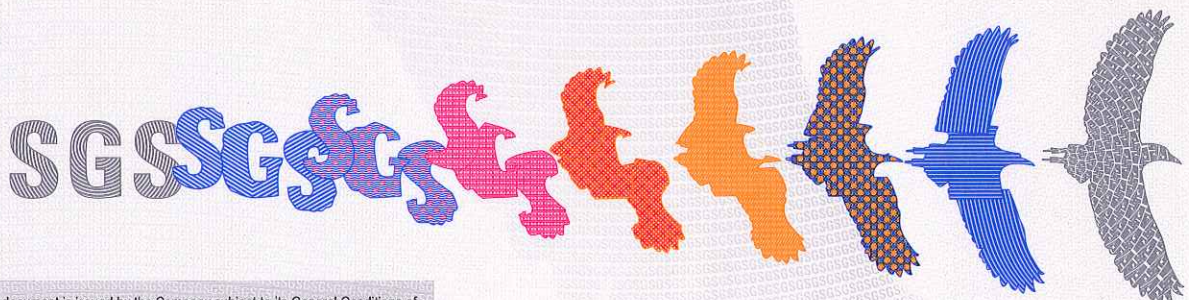
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# Radox Laboratories Ltd

**ISO 13485:2003**  
**EN ISO 13485:2012**



Issue 15

Detailed scope

**The design/development, manufacture, service and distribution of in-vitro diagnostic medical devices, in-vitro diagnostic test kits, in-vitro diagnostic reagents, calibrators and controls 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**  
**Radox Teoranta, Meenmore, Dungloe, Donegal, F94 TV06, Ireland**



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