



Scarlet NB UK Ltd
12 New Fetter Lane
London
EC4A 1JP
United Kingdom

Approved Body: Scarlet NB UK Ltd 8536

Legislation: Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002).

Reference: Medical Devices

The body is formally accredited against : EN ISO/IEC 17021 – Certification of management systems

Name of National Accreditation Body (NAB): UKAS - United Kingdom Accreditation Service

The accreditation covers the product categories and conformity assessment procedures concerned by this notification: Yes.

Product family, product /Intended use/Product range	Procedure/Modules	Annexes or articles of the directives [as modified by Part II of Schedule 2A to the Medical Devices Regulations 2002]	Limitations
*MD 1100 - General active medical devices			
*MD 1111 - Software	EC declaration of conformity (full quality assurance system)	Annex II	

Horizontal Technical Competence	Limitations
*MDS 7010 - Medical devices incorporating software /utilising software /controlled by software	