



Medicines & Healthcare products  
Regulatory Agency

Scarlet NB UK Ltd  
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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	