

UKCA Certificate - Full Quality Assurance System

Part II of The Medical Devices Regulations 2002, Annex II excluding Section 4 [as modified by Part 2 of Schedule 2A to The Medical Devices Regulations 2002]

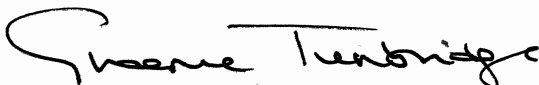
No. UKCA 02344
Issued To: LTE Scientific Ltd
Greenbridge Lane
Greenfield
Oldham
OL3 7EN
United Kingdom

In respect of:

The design, manufacture and final inspection of autoclaves.

On the basis of our examination of the quality assurance system under the requirements of Part II of the Medical Devices Regulations 2002, Annex II excluding Section 4 [as modified by Part II of Schedule 2A to The Medical Devices Regulations 2002]. The quality assurance system meets the requirements of the regulation. For the placing on the market of class III products an Annex II (modified as described above) Section 4 certificate is required.

For and on behalf of BSI, an Approved Body for the above Regulation (Approved Body Number 0086):



Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

First Issued: **1999-05-21**

Date: **2024-07-02**

Expiry Date: **2029-01-08**

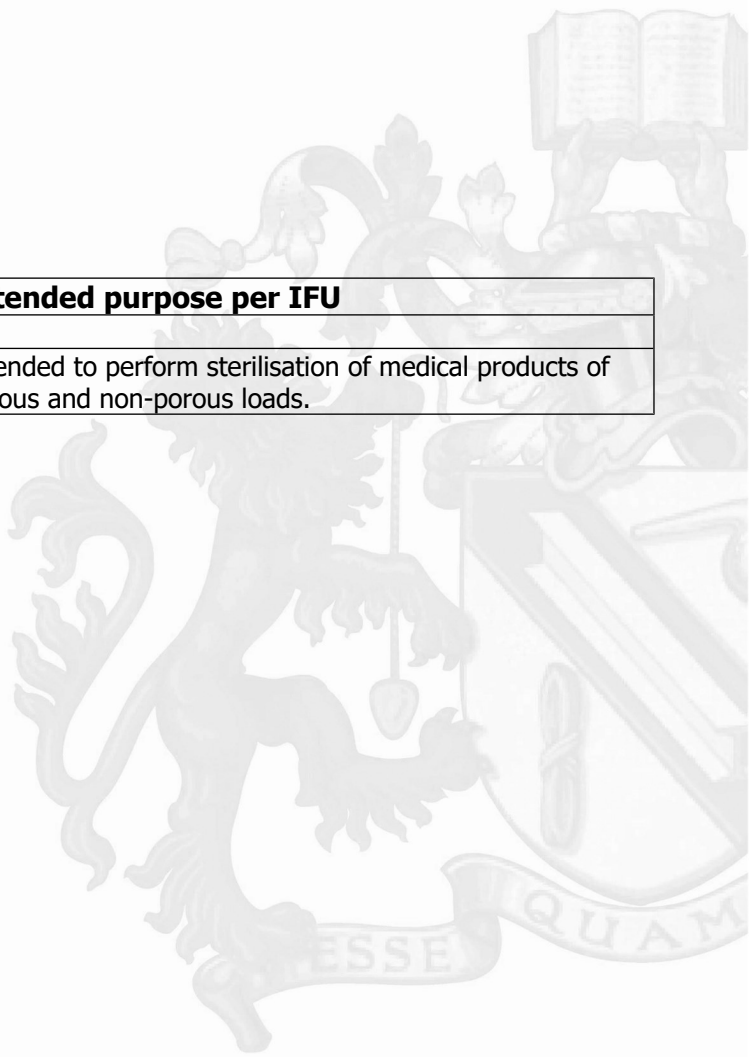
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Supplementary Information to UKCA 02344

Issued To: **LTE Scientific Ltd
Greenbridge Lane
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Device code	Device Name	Intended purpose per IFU
Class IIb		
MD 1107 MDS 7010	Autoclave	Intended to perform sterilisation of medical products of porous and non-porous loads.



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Certificate History

Certificate No: **UKCA 02344**
 Date: **2024-07-02**
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Date	Reference Number	Action
1999-05-21		Original Issue to Autoclave Control & Engineering Ltd
2002-10-16		Re-issued due to new legal entity and change of name to Autoclave Control & Engineering, A Division of LTE Scientific Ltd
2004-01-09		Re-issued due to a change of name to LTE Touchclave Systems, A Division of LTE Scientific Ltd. Five year review also performed
2004-10-20		Re-issued due to change of company name and address
2009-01-08	7305475	Certificate renewal
2010-03-21	7480396	Certificate upgrade from Annex V to Annex II
2013-12-19	8083831	Certificate renewal
2019-01-08	9700656	Certificate renewal
Current	30191670	Conversion from CE to UKCA certificate and renewal. Administrative update to previous date formatting.

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