

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

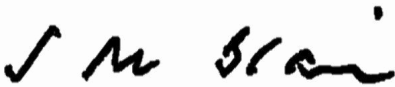
No. CE 02344
Issued To: **LTE Scientific Ltd**
Greenbridge Lane
Greenfield
Oldham
OL3 7EN
United Kingdom

In respect of:

The design and manufacture of Autoclaves

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):



Stewart Brain, Head of Compliance & Risk -
Medical Devices

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

Date: **2019-01-08**

Expiry Date: **2024-01-08**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

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Supplementary Information to CE 02344

Issued To:

**LTE Scientific Ltd
Greenbridge Lane
Greenfield
Oldham
OL3 7EN
United Kingdom**

NBOG code(s)	Device Description	Intended purpose
Class IIb		
MD 1107 MDS 7010	Autoclave	Touchclave – MP / PL/Lab - Intended to perform sterilization of medical products of porous and non-porous loads.

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

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Certificate History

Certificate No: CE 02344
Date: 2019-01-08
Issued To: LTE Scientific Ltd
 Greenbridge Lane
 Greenfield
 Oldham
 OL3 7EN
 United Kingdom

Date	Reference Number	Action
21 May 1999		Original Issue to Autoclave Control & Engineering Ltd
16 October 2002		Re-issued due to new legal entity and change of name to Autoclave Control & Engineering, A Division of LTE Scientific Ltd
09 January 2004		Re-issued due to a change of name to LTE Touchclave Systems, A Division of LTE Scientific Ltd. Five year review also performed
20 October 2004		Re-issued due to change of company name and address
08 January 2009	7305475	Certificate renewal
21 March 2010	7480396	Certificate upgrade from Annex V to Annex II
19 December 2013	8083831	Certificate renewal
Current	9700656	Certificate renewal

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