

EC Certificate - Product Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex VI

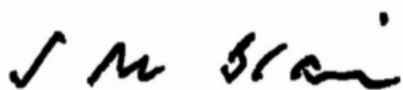
No. **CE 02154**
Issued To: **LCR Hallcrest**
Riverside Buildings
1 Dock Road
Connah's Quay
Deeside
Flintshire
CH5 4DS
United Kingdom

In respect of:

Those aspects of Annex VI relating to metrology in the final inspection of forehead thermometers

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex VI. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb products, an Annex III 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: **1998-11-16**

Date: **2018-09-21**

Expiry Date: **2023-11-15**

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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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List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

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Subcontractor:

Service(s) supplied

LCR Hallcrest, LLC
 1911 Pickwick Lane
 Glenview
 Illinois
 60026
 USA

Manufacture

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Certificate History

Certificate No: **CE 02154**
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Date	Reference Number	Action
16 November 1998		First issue.
25 October 2001		Change of Annex.
17 February 2004		Five year certificate renewal. New certificate format.
13 September 2004		Reissue to add two manufacturing subcontractors: Liquid Crystal Resources, LLC and B&H LCR.
18 March 2005		Change of company name. Removal of B&H LCR from subcontractors list.
07 November 2008	7005357	Certificate renewal. Change of company name from B&H Liquid Crystal Resources Ltd to LCR Hallcrest.
25 October 2013	8072366	Certificate renewal. Change subcontractor to LCR Hallcrest, LLC.
Current	8919489	Certificate renewal. Amend subcontractor address LCR Hallcrest, LLC to remove dba Hallcrest.

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