



DNV BUSINESS ASSURANCE

EC CERTIFICATE – PRODUCTION QUALITY ASSURANCE

Certificate No. 39003-2008-CE-NOR Rev. 2.0

This Certificate consists of 3 pages

This is to certify that the Quality Management System of

LCR Hallcrest, LLC

1911 Pickwick Lane, Glenview, IL 60026 USA

for production and final product inspection/testing of

Forehead Thermometers

has been assessed with respect to

the conformity assessment procedure described in Article 11.5 and Annex V (Module D1) of Council Directive 93/42/EEC on Medical Devices for the aspects of manufacture concerned with the conformity of the products with metrological requirements, as amended, and found to comply

Further details are given overleaf

Place and date:

Høvik, 04 November 2013

This Certificate is valid until:

08 September 2018

For DET NORSKE VERITAS CERTIFICATION AS
NORWAY



Ragnar Stranger Christiansen
Certification Manager

Notified Body No.:
0434

Aud Løken Eiklid
Technical Reviewer

This Certificate has been digitally signed. See www.dnv.com/digitalsignatures for more info

Notice: The certificate is subject to terms and conditions overleaf. Any significant changes in design or construction may render this certificate invalid.

If any person suffers loss or damage which is proved to have been caused by any negligent act or omission of Det Norske Veritas, then Det Norske Veritas shall pay compensation to such person for his proved direct loss or damage. However, the compensation shall not exceed an amount equal to ten times the fee charged for the service in question, provided that the maximum compensation shall never exceed USD 300.000. In this provision "Det Norske Veritas" shall mean the Foundation Det Norske Veritas as well as all its subsidiaries, directors, officers, employees, agents and any other acting on behalf of Det Norske Veritas.



Cert. No.: 39003-2008-CE-NOR
Rev. No.: 2.0
Project No.: PRJC-53184-2008-PRC-USA

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as “Forskrift for Medisinsk Utstyr” by the Norwegian Ministry of Health and Care Services.

Certificate history

Revision	Description	Issue Date
	Original certificate	2003-09-02
	Recertification	2008-09-26
1.0	Changes in the manufacturer's name and address	2010-10-07
2.0	Recertification	2013-09-08

Products covered by this Certificate

Product Description	Product Name	Class
Forehead Thermometers	1000 Digital series L300 Analog series	I measuring

The complete list of devices is filed with the Notified Body.

Sites covered by this certificate:

1911 Pickwick Lane, Glenview, IL 60026 USA



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Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform the local DNV Office of any intended updating of the quality system and DNV will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system DNV reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of DNV.

END OF CERTIFICATE

bsi.



Certificate

Product Quality Assurance



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 under the requirements of Council Directive 93/42/EEC, Annex VI, Section 3.2.
For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):

Gary Fenton, Global Assurance Director

First Issued: **16 Nov 1998**

Date: **25 Oct 2013**

Expiration Date: **15 Nov 2018**

Page: 1 of 1

Conditions of Approval

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive.
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.

...making excellence a habit.™

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: +44 (0)845 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL UK. A member of the BSI Group of Companies.

List of Significant Subcontractors

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

Certificate No. **CE 02154**
Date: **25 Oct 2013**
Issued to: **LCR Hallcrest Ltd**
Flintshire
United Kingdom

Subcontractor	Service(s) supplied
LCR Hallcrest, LLC dba Hallcrest 1911 Pickwick Lane Glenview Illinois 60026 USA	Manufacture