DNV BUSINESS ASSURANCE

EC CERTIFICATE – PRODUCTION QUALITY ASSURANCE

Certificate No. 2452-2013-CE-RGC-NA Rev. 1.0
This Certificate consists of 3 pages

This is to certify that the Quality Management System of

for production and final product inspection/testing of

Electronic Thermometers

has been assessed with respect to

the conformity assessment procedure described in Article 11.2.b and Annex V (Module D1) of Council Directive 93/42/EEC on Medical Devices, as amended, and found to comply

Further details are given overleaf

Place and date:
Høvik, 19 October 2015

This Certificate is valid until:
29 September 2018

for DNV GL BUSINESS ASSURANCE
NORWAY AS

NORWEGIAN ACCREDITATION
PROD 002

CE

Aud Løken Eiklid
Certification Manager

Notified Body No.:
0434

Sholeh Gheissar
Technical Reviewer

This Certificate has been digitally signed. See www.dnvgl.com/digitalsignature for more info

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
0	Original Certificate	2013-09-29
1	**Extension of Scope – New product added (in bold)**	**2015-10-19**

Products covered by this Certificate

Product Description	Product	Class
Infrared Thermometer	IT-901, IT-121, **IT-122, IT-123, IT-124, IT-125, IT-126, IT-127, IT-128, IT-129**	IIa
Digital Clinical Thermometer	DT-121, DT-122	IIa

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

Sites covered by this certificate

Site Name	Address

EU Representative

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