DNV BUSINESS ASSURANCE

EC CERTIFICATE – FULL QUALITY ASSURANCE SYSTEM

Certificate No. 73547-2010-CE-CZS-NA 6.0

This Certificate consists of 3 pages

This is to certify that the Quality Management System of

GCE s.r.o.

Žižkova 381, 583 81 Chotěboř, Czech Republic

for design, production and final product inspection/testing of

Medical Devices for use with Medical Gases

has been assessed with respect to
the conformity assessment procedure described in Article 11.3.a and Annex II excluding section 4 (Module H) of Council Directive 93/42/EEC on Medical Devices, as amended, and found to comply

Further details are given overleaf

Place and date:
Høvik, 26 March 2015

For DNV GL Business Assurance Norway AS

Aud Løken Eiklid
Certification Manager

NORWEGIAN ACCREDITATION
PROD 002

CE

Notified Body No.:
0434

This Certificate is valid until:
30 March 2020

Sholeh Gheissar
Technical Reviewer

This Certificate has been digitally signed. See www.dnv.com/digitalsignatures 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
	Original certificate	2005-06-01
	Recertification and merging of all devices and certificates. This certificate supersedes all former ones.	2010-03-30
1.0	Revised due to editorial updates	2010-06-08
2.0	• Reclassification of Terminal Units • New products added	2010-10-01
3.0	• New Product added	2010-11-25
4.0	• Revised due to editorial updates • New Product added	2011-02-01
5.0	• Change of Product Names and new model added • Reclassification of Terminal Units for scavenging of gases	2013-03-04
6.0	**Recertification**	**2015-03-26**

Products covered by this Certificate

Product Description	Product Name	Class
Medical devices for use with Medical Gases	Pressure regulators integrated with cylinder valves	IIb
	Cylinder valves	
	High Pressure Regulators	
	Terminal Unit	
	Ambulance Panel	
	Central gas supply system	
	Resuscitator	

Medical devices for use with Medical Gases	Flow-metering devices (Ball flow meters, Flow selectors)	IIa
	Humidifiers	
	Low pressure hoses	
	Low pressure regulators	
	Terminal Unit (for Anesthetic Gas Scavenging System)	
	Suction equipment (Suction ejectors, Vacuum regulators)	
	Demand Valve	
	Gas Switch	
	Gas Saver	

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

Sites covered by this certificate

Site Name	**Address**
GCE s.r.o.	Žižkova 381, 583 81 Chotěboř, Czech Republic

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 GL Office of any intended updating of the quality system and DNV GL 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 GL 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 GL.

END OF CERTIFICATE