

Certificate No.:  
**262513-2018-AQ-CZS-NA-PS Rev. 0.0**

Project No.:  
**PRJC-358993-2012-MS-CZE**

Initial Certification Date:  
**11 May 2018**

Valid Until:  
**11 May 2021**

This is to certify that the management system of:

## **GCE Holding AB**

Källvattengatan 9  
200 21 MALMØ  
Sweden

With sites as listed overleaf.

Complies with the requirements of:

## **ISO 13485:2016/NS-EN ISO 13485:2016**

The Certificate is valid for the following scope:

**Design, production, sales, distribution and service of medical devices to control flow and pressure as well as devices for usage of medical gases in health services in following product groups: Pressure regulators, Terminal units, Suction equipment, Hoses, Cylinder and combination valves, Flow meters, Central Gas Manifolds, Accessories.**

Place and Date:  
**Høvik, 15 May 2018**



For:  
**DNV GL NEMKO PRESAFE AS**

**Eugenie Winger Husebye**

The Certificate has been digitally signed.  
See [www.presafe.com/digital\\_signatures](http://www.presafe.com/digital_signatures) for more info

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

# Management System Certificate

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| Site Name     | Address  | Site Scope   |
|---------------|--|--|
| GCE s.r.o.    | Žižkova 381,583 01,Chotěboř,Czech Republic                 | Design, production, sales, distribution and service of medical devices to control flow and pressure as well as devices for usage of medical gases in health services in following product groups: Pressure regulators, Terminal units, Suction equipment, Hoses, Cylinder and combination valves, Flow meters, Central Gas Manifolds, Accessories. |
| GCE GmbH      | Weyherser Weg 8,36043,Fulda,Germany                        | Sales, distribution and service of medical devices to control flow and pressure as well as devices for usage of medical gases in health services   |
| GCE Norden AB | Källvattengatan 9,SE-200 21,Malmö,Sweden                   | Sales, distribution, customization and service of medical devices to control flow and pressure as well as devices for usage of medical gases in health services  |
| GCE SAS       | 70, Rue du Puits Charles,58403,LA CHARITE SUR LOIRE,France | Sales and distribution of medical devices to control flow and pressure as well as devices for usage of medical gases in health services. Service of concentrators.   |

End of Certificate