



# Certificate

No. Q5 073169 0009 Rev. 02

**Holder of Certificate:** **Ganshorn Medizin Electronic GmbH**  
Industriestrasse 6-8  
97618 Niederlauer  
GERMANY

**Certification Mark:**



**Scope of Certificate:** **Design and Development, Production, Service and Sale of devices and software for lung function analysis as well as ergometer**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:Q5 073169 0009 Rev. 02](http://www.tuvsud.com/ps-cert?q=cert:Q5 073169 0009 Rev. 02)

**Report No.:** 713297549

**Valid from:** 2023-09-27

**Valid until:** 2026-09-26

**Date,** 2023-09-27

Christoph Dicks  
Head of Certification/Notified Body

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**Applied Standard(s):**

EN ISO 13485:2016  
Medical devices - Quality management systems -  
Requirements for regulatory purposes  
(ISO 13485:2016)  
DIN EN ISO 13485:2016

**Facility(ies):**

**Ganshorn Medizin Electronic GmbH**  
Industriestrasse 6-8, 97618 Niederlauer, GERMANY

Design and Development, Production, Service and Sale  
of devices and software for lung function analysis  
as well as Design and Development for ergometer

**ergosana GmbH**

Truchtelfinger Straße 17, 72475 Bitz, GERMANY

Production, Service and Sale of Ergometers

**Parameters:**

n/a