



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
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Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 073169 0005 Rev. 01

Manufacturer:

Ganshorn Medizin Electronic GmbH

Industriestrasse 6-8

97618 Niederlauer

GERMANY

Facility(ies):

Ganshorn Medizin Electronic GmbH

Industriestrasse 6-8, 97618 Niederlauer, GERMANY

**Product Category(ies): Devices and software for
pulmonary function diagnostics**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

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Date,

2018-08-30

Stefan Preiß