Declaration of EC Conformity

GANSHORN
Medizin Electronic GmbH

Manufacturer: **Ganshorn Medizin Electronic GmbH**
Address: **Industriestraße 6-8**
97618 Niederlauer, Germany

declares, on it's own responsibility, that the following product:

Product designation: **Pulmonary function diagnostic system**

Product name: **SpiroScout**

Is in conformity with the Medical Device Directive:

Medical Device Directive 93 / 42 / EEC

According to Annex IX of this Directive the SpiroScout is classified as:

Device: **Active medical device - class IIa**

A Conformity Assessment Procedure according to Annex II of the Medical Device Directive 93/42/EEC (with exception clause 4) was conducted with the Notified Body:

TÜV SÜD
Product Services GmbH
Notified Body Regulatory Code 0123
Ridlerstraße 65
80339 München

CE 0123

GANSHORN MEDIZIN
ELECTRONIC GMBH

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Jürgen Behringer (CEO)
Chief Executive Officer

Niederlauer, November 01, 2018

Note: This document version is valid until November 2023