



GANSHORN

Medizin Electronic GmbH

Declaration of EC Conformity

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: **PowerCube**
Product execution **PowerCube Body+**
PowerCube Diffusion+

Is in conformity with the Medical Device Directive:

Medical Device Directive 93 / 42 / EEC

According to Annex IX of this Directive the PowerCube Body+ / PowerCube Diffusion+ 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 Service GmbH
Notified Body Regulatory Code 0123
Ridlerstraße 65
80339 München

GANSHORN MEDIZIN
ELECTRONIC GMBH



GANSHORN
MEDIZIN ELECTRONIC

GANSHORN Medizin Electronic GmbH
Industriestrasse 6 - 8 · D-97618 Niederlauer
Tel: +49 9771 6222 0 · Fax: +49 9771 6222 55


Jürgen Behringer
Chief Executive Officer

Niederlauer, January 19, 2018



Consumables & Options

Standard Consumables for PWC Body+

01 942 0724	Permanent breathing tube
01 942 0650	GANSHORN PFT Bacterial filters
01 942 0656	GANSHORN Safe filter pack Filter with nose clip
01 942 0655	GANSHORN Extra Safe filter pack Filter with nose clip and extra mouth piece
01 941 0901	Nose Clip
01 320 0301	Diffusion (for Package 05 420 0000)
01 942 0862	Pressure regulator for Single Breath Diffusion
01 433 0015	Provocation Provo.X (integrated in the Body-box) Bronchial inhalation provocation dosimeter complete: Nebulizer, external control unit, low pressure tube, pressure generator
01 544 0050	P0,1 / Pmax
01 544 0020	ROCC
01 320 0302	Rhinomanometry
01 320 0305	Compliance+
01 320 0306	FRC Washout
05 420 2311	PowerCube-Body+ Wheel- Chair option

GANSHORN MEDIZIN
ELECTRONIC GMBH

Jürgen Behringer
Chief Executive Officer



GANSHORN
MEDIZIN ELECTRONIC

GANSHORN Medizin Electronic GmbH
Industriestrasse 6-8 • D-97618 Niederlauer
Tel: +49 9771 6222 0 • Fax: +49 9771 6222 55

Niederlauer, January 19, 2018

