

**Declaration of Conformity
Directive 93/42/EEC on Medical Device (MDD)**

Manufacturer: GANSHORN Medizin Electronic GmbH,
Manufacturing Site: Industriestrasse 6-8, 97618 Niederlauer, Germany
SRN: DE-MF-000006566
QMS: Q5 073169 0009
EC-Certificate: G1 073169 0005
Notified Body: TÜV SÜD Product Service GmbH, ID 0123
 Ridlerstraße 65 80339 München / Munich
 Germany

Device Information	
Trade Name	PowerCube+ Series <ul style="list-style-type: none"> • PowerCube Body+ • PowerCube Diffusion+
Product Type	Pulmonary function analyser
REF Number	050000000
Intended Purpose	A device used to measure the function of the respiratory system in adults and compliant children. It usually includes a spirometer with flow-sensing devices, a gas analyser for evaluation of absolute lung volumes and gas-diffusing capacity of the lungs, and computer capabilities for data processing and recording; a total-body plethysmograph to measure both lung volumes and airway resistance may be included. The device is mostly used for outpatient or presurgical screening and may also be used in the diagnosis and evaluation of common diseases in children (e.g., asthma).
Risk Class according to Annex VIII MDR	Ila
GMDN Code	35282
EMDN Code	Z121590
Basic-UDI-DI	7613365PWCBD2Y

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Device Information	
UDI-DI / Product Description	
0 7613365 50030	PwC Diffusion+ (MultiX + Spiro(Basis) + Diffusion)
0 7613365 50031	PwC Diffusion+ (MultiX + Spiro(Basis) + Diffusion + FRC (N2 Washout))
0 7613365 50032	PwC Diffusion+ (MultiX + Spiro(Basis))
0 7613365 50033	PwC Diffusion+(Haeberle + Spiro(Basis) + Diffusion)
0 7613365 50034	PwC Diffusion+ (Haeberle + Spiro(Basis) + Diffusion + FRC (N2 Washout))
0 7613365 50035	PwC Diffusion+ (Haeberle + Spiro(Basis))
0 7613365 50036	PwC Body+ (MultiX + Standard Cabin+ Spiro(Basis))
0 7613365 50037	PwC Body+ (MultiX + Standard Cabin + Spiro(Basis) + Diffusion)
0 7613365 50038	PwC Body+ (MultiX + Standard Cabin + Spiro(Basis) + Diffusion+ FRC (N2 Washout))
0 7613365 50039	PwC Body+ (MultiX + Wheelchair Cabin+ Spiro(Basis))
0 7613365 50040	PwC Body+ (MultiX + Wheelchair Cabin + Spiro(Basis) + Diffusion)
0 7613365 50041	PwC Body+ (MultiX + Wheelchair Cabin + Spiro(Basis) + Diffusion+ FRC (N2 Washout))
0 7613365 50042	PwC Body+ (MultiX + XL Cabin+ Spiro(Basis))
0 7613365 50043	PwC Body+ (MultiX + XL Cabin + Spiro(Basis) + Diffusion)
0 7613365 50044	PwC Body+ (MultiX + XL Cabin + Spiro(Basis) + Diffusion+ FRC (N2 Washout))
0 7613365 50045	PwC Body+ (Haeberle + Standard Cabin+ Spiro(Basis))
0 7613365 50046	PwC Body+ (Haeberle + Standard Cabin+ Spiro(Basis) + Diffusion)
0 7613365 50047	PwC Body+ (Haeberle + Standard Cabin+ Spiro(Basis) + Diffusion+ FRC (N2 Washout))
0 7613365 50048	PwC Body+ (Haeberle + Wheelchair Cabin+ Spiro(Basis))
0 7613365 50049	PwC Body+ (Haeberle + Wheelchair Cabin+ Spiro(Basis) + Diffusion)
0 7613365 50050	PwC Body+ (Haeberle + Wheelchair Cabin+ Spiro(Basis) + Diffusion+ FRC (N2 Washout))
0 7613365 50051	PwC Body+ (Haeberle + XL Cabin+ Spiro(Basis))
0 7613365 50052	PwC Body+ (Haeberle + XL Cabin+ Spiro(Basis) + Diffusion)
0 7613365 50053	PwC Body+ (Haeberle + XL Cabin+ Spiro(Basis) + Diffusion+ FRC (N2 Washout))

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Device Information	
Applied Standard and common specifications	<p>IEC 60601-1-2:2007 ed. 3.0 ISO 13485:2016 ed. 3.0 IEC 60601-1:2005 + Cor1:2006 + Cor2:2007 + A1:2012 + A1:2012/Cor1:2014 + A2:2020 DIN EN 60601-1-6:2021-11 DIN EN 62366-1:2021-08 ANSI AAMI HE75:2018 Human factors engineering - Design of medical devices IEC 62304:2015 ed. 1.1 / IEC 62304:2021 → AMD1:205-06 ISO 15223-1:2021 ed. 4.0 ISO 20417:2021 ed. 1.0 DIN EN 22248 ISO 23747:2007 ISO 23747:2015 ISO 26782:2009 ed. 1.0 EN 13826:2003 ISO 14971:2019 EN ISO 10993-1:2020 EN ISO 10993-5:2009 ISO 10993-10:2021 DIN EN ISO 10993-18 2020 EN-ISO-10993-23-2021 DIN EN ISO 18562-1:2020-05 ISO 18562-2:2017-03 ISO 18562-3:2017-03 ISO 18562-4:2017-03 DIN EN ISO 14155:2021-05 SNG CEN ISO/TR 20416:2020-09 2005, Volume 26, Number 1 2019, Volume 200, Issue 8 Spirometry: Standardization of Spirometry 2019</p>

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We, the undersigned, declare that the medical device described above is in conformity with the essential requirements of 93/42/EEC (MDD) Annex II excluding (4).

The products are CE marked with notified body number.



RoHS 2 and 3

We, the undersigned, further declare that the medical device described above is in conformity with the applicable provision of the *Directive 2011/65/EU "Restriction of the use of certain hazardous substances in electrical and electronic equipment"* and its amended *Directive 2015/863/EU*.

This declaration of conformity is issued under the sole responsibility of GANSHORN Medizin Electronic GmbH. This declaration supersedes any declaration issued previously for the same product.

Signed for on behalf of **GANSHORN Medizin Electronic GmbH**

Date of Issue: 2024-02-11

Place of Issue: Niederlauer, Germany



GANSHORN

SCHILLER GROUP

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Name: Sirimane Chatrojjanasakul

Title / Function: Head of Quality
Management and Regulatory Affairs

Signature:

Name: Dr. Stefan Ponto

Title / Function: Co-Chief Executive Officer

Signature:

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Appendix 01 List of compatible medical device(s) and accessories

GANSHORN REF No. as per Label	Accessory / Device name	Legal Manufacturer
019420660	SpiroDef Mouthpiece, PFT Bacterial Filter	GANSHORN Medizin Electronic GmbH
019410908	NoseClip	GANSHORN Medizin Electronic GmbH
019420664	SpiroDef Mouthpiece with NoseClip, pack of 100	GANSHORN Medizin Electronic GmbH
019420649	GANSHORN PFT Filter/round mouthpiece, pack of 100	GVS S.p.A.
019500540	Foam nose adapter, size small 12mm	Merz Medizintechnik GmbH
019500541	Foam nose adapter, size medium 15mm	Merz Medizintechnik GmbH
019500542	Foam nose adapter, size large 18mm	Merz Medizintechnik GmbH

Appendix 02 List of compatible non-medical device(s), spare parts and components

GANSHORN REF No. as per Label	Description / Device name
019420626	Permanent breathing tube
019500558	Gas analysis intermediate adapter for permanent breathing tube
019420869	GANSHORN pressure regulator for He/CO
019900521	Test gas cylinder (He/CO/O ₂ /N)
019420701	Gas cylinder trolley
019420009	3000ml calibration pump
019600835	Rubber adapter for calibration pump
019600928	Hose kit for Rhinomanometry for PowerCube+ Series
019500545	Mouthing for Rhinomanometry
019500548	Nasal olives (adults)
019500549	Nasal olives (children & teenagers)