

Declaration of Conformity Regulation (EU) 2017/745

Legal Manufacturer: GANSHORN Medizin Electronic GmbH
Industriestrasse 6-8, 97618 Niederlauer, Germany

SRN: DE-MF-000006566

QMS: Q5 073169 0009

EC-Certificate: G11 073169 0013

Notified Body: TÜV SÜD Product Service GmbH, ID 0123
Ridlerstraße 65 80339 München / Munich
Germany

Device Information			
Trade Name	<ul style="list-style-type: none"> • SpiroScout • SpiroScout SP • SpiroScout SP plus 		
Product Type	Spirometer		
Intended Purpose	<p>The Spirometry-Scout is a PC-based ultrasonic spirometer for measuring breath flow. The Spirometry-Scout in combination with a Spirometry software is intended for measuring and analysing lung function parameters.</p> <p>The Spirometry-Scout is intended for use in hospital and clinic settings.</p>		
Risk Class according to Annex VIII MDR	IIa		
GMDN Code	13680		
EMDN Code	Z121501		
Basic-UDI-DI	7613365SPSCT63		
Conformity Assessment acc. to MDR	Annex IX Chapters I and III		
REF Number	REF #	GTIN	Device Name
	044210001	0 7613365 50001 1 0 7613365 50002 8	SpiroScout
	013400562	0 7613365 50004 2	SpiroScout SP
	013400563	0 7613365 50003 5	SpiroScout SP plus

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Device Information				
System Version	SpiroScout Rev. F	Hardware Version <ul style="list-style-type: none"> • Sensor (Model V1) + Basisstation • Sensor (Model V3) Rhinomanometrie 	Firmware <ul style="list-style-type: none"> • Firmware USBase Version 1.08 for SpiroScout Rev. F Basisstation • V1 / V3 – Sensor: USCntl V.2.26.1 	Software LFX Spirometry Software
	SpiroScout SP Rev. A	Sensor (Model V1)	Firmware USCntl V.2.27	Spirometry Software SCHILLER
	SpiroScout SP plus Rev. D	Sensor (Model V1)	Firmware USCntl V.2.26.1	Spirometry Software SCHILLER
Applied Standard and common specifications	<p>EN ISO 13485:2016 EN 60601-1:2005+A1:2012 EN 60601-1-2:2015 EN 60601-1-6:2020 IEC 62366-1:2020 IEC 62304:2015 ISO 15223-1:2021 ISO 20417:2021 EN ISO 14971:2022 (ISO 14971:2019) EN ISO 10993-1:2018 DIN EN ISO 10993-5:2009 DIN EN ISO 10993-10:2023 ISO 10993-18:2020 EN ISO 10993-23:2021 ISO 18562-1:2017 ISO 18562-2:2017 ISO 18562-3:2017 ISO 18562-4:2017 DIN EN ISO 23747: 2015 ISO 26782: 2009 ISO 14155:2020 ISO/TR 20416 2005, Volume 26, Number 1 Spirometry: General considerations for lung function testing (ATS/ERS TASK FORCE: STANDARDISATION OF LUNG FUNCTION TESTING’) 2019, Volume 200, Issue 8 Spirometry: Standardization of Spirometry 2019 Update. An Official American Thoracic Society and European Respiratory Society Technical Statement</p>			

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We, the undersigned, declare that the medical device described above is in conformity with the applicable provision of the *MDR (EU) 2017/745: Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC*

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: 2023-11-07

Place of Issue: Niederlauer, Germany



GANSHORN
SCHILLER GROUP

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

Name: Dr. Stefan Ponto

Name: Sirimanee Chatrojjanasakul

Title / Function: Co-Chief Executive Officer

Title / Function: Head of Quality Management
and Regulatory Affairs

Signature:

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
019420620	ScoutTube	GANSHORN Medizin Electronic GmbH
019420656	GANSHORN safe filter pack (PFT Bacterial filter with NoseClip)	G.V.S
019420655	GANSHORN safe filter pack (PFT Bacterial filter with NoseClip and mouthpiece)	
019420660	SpiroDef Mouthpiece, PFT Bacterial Filter	GANSHORN Medizin Electronic GmbH
019420661	SpiroDef ScoutTube, PFT Bacterial Filter	GANSHORN Medizin Electronic GmbH
019410908	NoseClip	GANSHORN Medizin Electronic GmbH
019420649	GANSHORN PFT filter / round mouthpiece	
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
012370154	Mask 0-6 months	Intersurgical Ltd.
012370155	Mask 6 months – 2 years	Intersurgical Ltd.
012370156	Mask >2 years	Intersurgical Ltd.

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
019500831	SpiroSensor cable
019500826	USB cable to PC
019420009	3000 ml calibration pump
019600835	Rubber adapter for calibration pump
019500548	Nasal olives (adults)
019500549	Nasal olives (children & teenagers)
012370170	Dead space reducer 5 mm
012370171	Dead space reducer 8 mm