

# Konformitätserklärung | Declaration of Conformity

Wir, als Hersteller |  
We as manufacturer

Geratherm Respiratory GmbH  
Kasernenstraße 4  
97688 Bad Kissingen  
Deutschland | Germany  
EUDAMED SRN: DE-MF-00006818  
DE-PR-000020481

## Spirostik Blue

Zweckbestimmung: Gerät zur Bestimmung der statischen und dynamischen Lungenvolumina |  
Intended use: Device for determining static and dynamic lung volumes

erklären in alleiniger Verantwortung, dass das Produkt |  
declare under sole responsibility that the product

REF: 356246 (alte | old REF: 40.070)  
UDI-DI: 04065803002008

Seriennummer (Produktionsjahr) | Serial number (year of production):  
von | from 2111xxxxx (2025) bis | to 2111xxxxx (2026)

TD-Version | TD version: 1.0.5.2

Basis | Basic UDI-DI:  
EMDN:  
UMDNS:  
MDR Code:

4065803002GR01ACNK  
Z12150101  
13-674  
MDA 0204

auf das sich diese Erklärung bezieht, sowie als Bestandteil der Systeme in Anhang II, |  
to which this declaration relates, and as a component of the systems of Annex II,

Medizinprodukt der Risikoklasse | Medical Device of risk class  
**Ila,**

gemäß Regel 10 nach Anhang VIII der Verordnung (EU) 2017/745 (MDR) klassifiziert wird als |  
according to Rule 10 of Annex VIII of Regulation (EU) 2017/745 (MDR) the product is classified as

hergestellt, freigegeben und in Verkehr gebracht wird unter |  
is manufactured, released, and placed on the market under

Verordnung (EU) 2017/745 (MDR) |  
Regulation (EU) 2017/745 (MDR)

und die Anforderungen erfüllt gemäß |  
and complies with the requirements according to

Richtlinie | Directive 2011/65/EU (RoHS).

Das Produkt durchlief erfolgreich ein Konformitätsbewertungsverfahren nach |  
The product successfully passed a conformity assessment procedure according to

Anhang IX, Kapitel 1 der Verordnung (EU) 2017/745 (MDR) |  
Annex IX, Chapter 1 of the Regulation (EU) 2017/745 (MDR)

und ist gekennzeichnet mit der Konformitätsmarke |  
and is labeled with the conformity mark



Benannte Stelle: |  
Notified Body:

SLG Prüf- und Zertifizierungs GmbH  
Burgstädter Straße 20  
09232 Hartmannsdorf  
Deutschland | Germany

Wir als Hersteller operieren unter einem zertifiziertem Qualitätsmanagementsystem gemäß |  
We as manufacturer operate under a certified quality management system according to

DIN EN ISO 13485:2021-12.

Bad Kissingen, 2025-JAN-03

Florian Dassel

Geschäftsführer und Verantwortliche Person (Konformitätsbewertung)  
Managing Director and Person Responsible for Regulatory Compliance (Conformity Assessment)

## Anhang I

Komponenten des Medizinproduktes

## Annex I

Components of the Medical Device

# Spirostik Blue

REF: 356246 (alte | *old* REF: 40.070)

Diese Konformitätserklärung gilt auch für die folgenden Komponenten, die von der Geratherm Respiratory GmbH für das in dieser Konformitätserklärung genannte Medizinprodukt hergestellt oder zusammengestellt werden.

*This declaration of conformity also applies to the following components, which are manufactured or assembled by Geratherm Respiratory GmbH for the medical device mentioned in this declaration of conformity.*

REF   REF	Alte REF   Old REF	UDI-DI   UDI-DI	Komponente   Component
164930	n/a	n/a	Spirostik Blue, Kopf   Spirostik Blue, Head
541782	n/a	n/a	Spirostik Blue, Handgriff   Spirostik Blue, Handle

Anhang II

Zugeordnete Systeme des

Spirostik Blue

REF: 356246 (alte | old REF: 40.070)

Dieses Produkt kann separat oder als Bestandteil von folgenden Systemen, einschliesslich deren (länderspezifischen) Produktkonfigurationen und möglichen Varianten verkauft werden.

This product may be sold separately or as part of the following systems including their (country-specific product) configurations and possible variants.

Systeme | Systems:

REF   REF	Alte REF   Old REF	UDI-DI   UDI-DI	System   System	Nachweis   Evidence
571442	40.075	04065803004002	Spirostik Blue, Disposable	SPB_II-1_P33-01_Rx_(Art22SpiroBlueDis)
375098	40.076	04065803004019	Spirostik Blue, Reusable	SPB_II-1_P33-02_Rx_(Art22SpiroBlueReu)

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## Anhang III

### Normen und Regularien

Hiermit wird bestätigt, dass für den Produktlebenszyklus des

## Annex III

### Standards and regulations

It is hereby confirmed that for the product life cycle of the

# Spirostik Blue

REF: 356246 (alte | old REF: 40.070)

zur Bewertung der Konformität und Erfüllung der grundlegenden Anforderungen folgende Normen und Regularien herangezogen wurden.

the following standards and regulations have been used to assess conformity and compliance with the essential requirements.

Norm / Regulierung   Standard / regulation	Jahr   Year	Kurzbeschreibung   Short description
DIN EN 60529:2014-09 + Berichtigung 1: 2017-02   Correction 1: 2017-02 + Berichtigung 1: 2019-06   Correction 2: 2019-06	2014	Schutzarten durch Gehäuse (IP-Code) + Berichtigung zu DIN EN 60529 (VDE 0470-1):2014-09 + Schutzarten durch Gehäuse (IP-Code)   Degrees of protection provided by enclosures (IP Code) + Corrigendum to DIN EN 60529 (VDE 0470-1):2014-09, + Degrees of protection provided by enclosures (IP Code)
DIN EN 60601-1	2013	Medizinische elektrische Geräte - Teil 1: Allgemeine Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale   Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
DIN EN 60601-1-2	2016	Medizinische elektrische Geräte - Teil 1-2: Allgemeine Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale - Ergänzungsnorm: Elektromagnetische Störgrößen - Anforderungen und Prüfungen   Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests
DIN EN 60601-1-6	2021	Medizinische elektrische Geräte - Teil 1-6: Allgemeine Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale - Ergänzungsnorm: Gebrauchstauglichkeit (IEC 60601-1-6:2010 + A1:2013 + A2:2020); Deutsche Fassung EN 60601-1-6:2010 + A1:2015 + A2:2021   Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability (IEC 60601-1-6:2010 + A1:2013 + A2:2020); German version EN 60601-1-6:2010 + A1:2015 + A2:2021
DIN EN 62304	2016	Medizingeräte-Software - Software-Lebenszyklus-Prozesse   Medical device software - Software life-cycle processes
DIN EN 62353	2015	Medizinische elektrische Geräte - Wiederholungsprüfungen und Prüfung nach Instandsetzung von medizinischen elektrischen Geräten   Medical electrical equipment - Recurrent test and test after repair of medical electrical equipment
DIN EN 62366-1	2021	Medizinprodukte - Teil 1: Anwendung der Gebrauchstauglichkeit auf Medizinprodukte (IEC 62366-1:2015 + COR1:2016 + A1:2020); Deutsche Fassung EN 62366-1:2015 + AC:2015 + A1:2020   Medical devices - Part 1: Application of usability engineering to medical devices (IEC 62366-1:2015 + COR1:2016 + A1:2020); German version EN 62366-1:2015 + AC:2015 + A1:2020
DIN EN ISO 10993-1	2021	Biologische Beurteilung von Medizinprodukten - Teil 1: Beurteilung und Prüfungen im Rahmen eines Risikomanagementsystems (ISO 10993-1:2018, einschließlich korrigierte Fassung 2018-10); Deutsche Fassung EN ISO 10993-1:2020   Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2018, including corrected version 2018-10); German version EN ISO 10993-1:2020
DIN EN ISO 18562-1	2020	Beurteilung der Biokompatibilität der Atemgaswege bei medizinischen Anwendungen – Teil 1: Beurteilung und Prüfung innerhalb eines Risikomanagement-Prozesses (ISO 18562-1:2017); Deutsche Fassung EN ISO 18562-1:2020   Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 1: Evaluation and testing within a risk management process (ISO 18562-1:2017); German version EN ISO 18562-1:2020

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# Declaration of Conformity – Spirostik Blue

Norm / Regulierung   Standard / regulation	Jahr   Year	Kurzbeschreibung   Short description
DIN EN ISO 18562-2	2020	Beurteilung der Biokompatibilität der Atemgaswege bei medizinischen Anwendungen - Teil 2: Prüfungen für Emissionen von Partikeln (ISO 18562-2:2017); Deutsche Fassung EN ISO 18562-2:2020   <i>Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 2: Tests for emissions of particulate matter (ISO 18562-2:2017); German version EN ISO 18562-2:2020</i>
DIN EN ISO 18562-3	2020	Beurteilung der Biokompatibilität der Atemgaswege bei medizinischen Anwendungen - Teil 3: Prüfungen für Emissionen von flüchtigen organischen Verbindungen (VOCs) (ISO 18562-3:2017); Deutsche Fassung EN ISO 18562-3:2020   <i>Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 3: Tests for emissions of volatile organic compounds (VOCs) (ISO 18562-3:2017); German version EN ISO 18562-3:2020</i>
DIN EN ISO 13485:2021-12	2021	Medizinprodukte - Qualitätsmanagementsysteme - Anforderungen für regulatorische Zwecke (ISO 13485:2016); Deutsche Fassung EN ISO 13485:2016 + AC:2018 + A11:2021   <i>Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016); German version EN ISO 13485:2016 + AC:2018 + A11:2021</i>
DIN EN ISO 14971	2022	Medizinprodukte - Anwendung des Risikomanagements auf Medizinprodukte (ISO 14971:2019); Deutsche Fassung EN ISO 14971:2019 + A11:2021   <i>Medical devices - Application of risk management to medical devices (ISO 14971:2019); German version EN ISO 14971:2019 + A11:2021</i>
DIN EN ISO 15223-1	2022	Medizinprodukte - Symbole zur Verwendung im Rahmen der vom Hersteller bereitzustellenden Informationen - Teil 1: Allgemeine Anforderungen (ISO 15223-1:2021); Deutsche Fassung EN ISO 15223-1:2021   <i>Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements (ISO 15223-1:2021); German version EN ISO 15223-1:2021</i>
DIN EN ISO 23747	2015	Anästhesie- und Beatmungsgeräte - Spirometer für den expiratorischen Spitzenfluss zur Bewertung der Lungenfunktion bei spontan atmenden Menschen   <i>Anaesthetic and respiratory equipment - Peak expiratory flow meters for the assessment of pulmonary function in spontaneously breathing humans</i>
DIN EN ISO 26782	2010	Anästhesie und Beatmungsgeräte - Spirometer zur Messung des zeitbezogenen forcierten Expirationsvolumens beim Menschen   <i>Anaesthetic and respiratory equipment - Spirometers intended for the measurement of time forced expired volumes in humans</i>
DIN EN ISO 780	2016	Verpackung - Versandverpackung - Graphische Symbole für die Handhabung und Lagerung von Packstücken Verpackung - Versandverpackung - Graphische Symbole für die Handhabung und Lagerung von Packstücken   <i>Packaging - Distribution packaging - Graphical symbols for handling and storage of packages</i>
DIN EN ISO 17664-1	2021	Aufbereitung von Produkten für die Gesundheitsfürsorge - Vom Medizinprodukt-Hersteller bereitzustellende Informationen für die Aufbereitung von Medizinprodukten - Teil 1: Kritische und semi-kritische Medizinprodukte (ISO 17664-1:2021); Deutsche Fassung EN ISO 17664-1:2021   <i>Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices - Part 1: Critical and semi-critical medical devices (ISO 17664-1:2021); German version EN ISO 17664-1:2021</i>
ISO 17664-2	2021	Aufbereitung von Produkten für die Gesundheitsfürsorge - Vom Medizinprodukt-Hersteller bereitzustellende Informationen für die Aufbereitung von Medizinprodukten - Teil 2: Nicht kritische Medizinprodukte   <i>Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices - Part 2: Non-critical medical devices</i>
DIN EN ISO 20417	2022	Medizinprodukte - Anforderungen an vom Hersteller bereitzustellende Informationen (ISO 20417:2021, korrigierte Fassung 2021-12); Deutsche Fassung EN ISO 20417:2021   <i>Medical devices - Information to be supplied by the manufacturer (ISO 20417:2021, Corrected version 2021-12); German version EN ISO 20417:2021</i>
EU-Richtlinie 2011/65/EU   EU Directive 2011/65/EU	2011	Richtlinie 2011/65/EU des Europäischen Parlaments und des Rates vom 8. Juni 2011 zur Beschränkung der Verwendung bestimmter gefährlicher Stoffe in Elektro- und Elektronikgeräten (RoHS)   <i>Directive 2011/65/eu of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)</i>
EU-Richtlinie 2012/19/EG   EU Directive 2012/19/EC	2012	Richtlinie 2012/19/EU des europäischen Parlaments und des Rates vom 4. Juli 2012 über Elektro- und Elektronik-Altgeräte (WEEE)   <i>Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE)</i>

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# Declaration of Conformity – Spirostik Blue

Norm / Regulierung   Standard / regulation	Jahr   Year	Kurzbeschreibung   Short description
EU-Richtlinie 67/548/EWG   EU Directive 67/548/EEC	1967	Richtlinie 67/548/EWG DES RATES vom 27. Juni 1967 zur Angleichung der Rechts- und Verwaltungsvorschriften für die Einstufung, Verpackung und Kennzeichnung gefährlicher Stoffe   Council Directive (EEC) 67/548 of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances
EU-Richtlinie 80/181/EWG   EU Directive 80/181/EEC	1980	Richtlinie 80/181/EWG des Rates vom 20. Dezember 1979 zur Angleichung der Rechtsvorschriften der Mitgliedstaaten über die Einheiten im Messwesen und zur Aufhebung der Richtlinie 71/354/EWG   Council 80/181/EEC Directive of 20 December 1979 on the approximation of the laws of the Member States relating to units of measurement and on the repeal of Directive 71/354/EEC
Verordnung (EU) 2017/745 (MDR)   Regulation (EU) 2017/745 (MDR)	2017	Verordnung (EU) 2017/745 des Europäischen Parlaments und des Rates (MDR)   Regulation (EU) 2017/745 of the European Parliament and of the Council (MDR)
EU-Verordnung 1907/2006/EG   EU Regulation 1907/2006/EC	2006	Verordnung (EG) Nr. 1907/2006 des europäischen Parlaments und des Rates vom 18. Dezember 2006 zur Registrierung, Bewertung, Zulassung und Beschränkung chemischer Stoffe (REACH), zur Schaffung einer Europäischen Chemikalienagentur, zur Änderung der Richtlinie 1999/45/EG und zur Aufhebung der Verordnung (EWG) Nr. 793/93 des Rates, der Verordnung (EG) Nr. 1488/94 der Kommission, der Richtlinie 76/769/EWG des Rates sowie der Richtlinien 91/155/EWG, 93/67/EWG, 93/105/EG und 2000/21/EG der Kommission   Regulation (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC
Durchführungsverordnung (EU) 2021/2226 der Kommission   Commission implementing regulation (EU) 2021/2226	2021	Durchführungsverordnung (EU) 2021/2226 der Kommission vom 14. Dezember 2021 mit Durchführungsbestimmungen zur Verordnung (EU) 2017/745 des Europäischen Parlaments und des Rates hinsichtlich elektronischer Gebrauchsanweisungen für Medizinprodukte   Commission implementing regulation (EU) 2021/2226 of 14 December 2021 laying down rules for the application of Regulation (EU) 2017/745 of the European Parliament and of the Council as regards electronic instructions for use of medical devices
EU-Richtlinie 2014/53/EU   EU Directive 2014/53/EU	2014	Richtlinie 2014/53/EU des europäischen Parlamentes und des Rates vom 16. April 2014 über die Harmonisierung der Rechtsvorschriften der Mitgliedstaaten über die Bereitstellung von Funkanlagen auf dem Markt und zur Aufhebung der Richtlinie 1999/5/EG (RED)   Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC (RED)
ATS/ERS: Standardisation of the measurement of lung volumes	2005	Wanger J, et al. „Standardisation of the measurement of lung volumes“. Nummer 3 der Reihe „ATS/ERS Task Force: Standardisation of Lung Function Testing“. Eur Respir J 2005; 26: 511–522   Wanger J, et al. „Standardisation of the measurement of lung volumes“. Number 3 in this Series „ATS/ERS Task Force: Standardisation of Lung Function Testing“. Eur Respir J 2005; 26: 511–522

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Déclaration de conformité |  
Declaration of Conformity

Nous, en tant que fabricant |  
We as manufacturer

Geratherm Respiratory GmbH  
Kasernenstraße 4  
97688 Bad Kissingen  
Allemagne | Germany  
EUDAMED SRN: DE-MF-000006818  
DE-PR-000020481

Spirostik Blue

Utilisation prévue: Appareil permettant de déterminer les volumes  
pulmonaires statiques et dynamiques |  
Intended use: Device for determining static and dynamic lung volumes

déclarons sous notre seule responsabilité que le  
produit |  
declare under sole responsibility that the product

REF: 356246 (ancien | old REF: 40.070)  
UDI-DI: 04065803002008

Numéro de série (année de production) | Serial number (year of production):  
de | from 2111xxxxx (2025) à | to 2111xxxxx (2026)

TD version | TD version: 1.0.5.2

Basic UDI-DI:  
EMDN:  
UMDNS:  
MDR Code:

065803002GR01ACNK  
Z12150101  
13-674  
MDA 0204

auquel se rapporte la présente déclaration, |  
to which this declaration relates,

est classé, conformément à la règle 10 de l'annexe  
VIII du règlement (UE) 2017/745 (MDR) |  
according to Rule 10 of Annex VIII of Regulation  
(EU) 2017/745 (MDR) the product is classified as

comme dispositif médical de la classe de risque | Medical Device  
of risk class  
**Ila,**

est fabriqué, libéré et mis sur le marché en vertu de  
la |  
is manufactured, released, and placed on the market  
under

Règlement (UE) 2017/745 (MDR) |  
Regulation (EU) 2017/745 (MDR)

et répondant aux exigences selon |  
and complies with the requirements according to

Directive | Directive 2011/65/EU (RoHS).

Le produit a passé avec succès une procédure  
d'évaluation de la conformité selon |  
The product successfully passed a conformity  
assessment procedure according to

l'annexe IX, chapitre 1 du règlement (UE) 2017/745 (MDR) |  
Annex IX, Chapter 1 of the Regulation (EU) 2017/745 (MDR)

et porte la marque de conformité |  
and is labeled with the conformity mark



Organisme désigné: |  
Notified Body:

SLG Prüf- und Zertifizierungs GmbH  
Burgstädter Straße 20  
09232 Hartmannsdorf  
Allemagne | Germany

En tant que fabricant, nous opérons sous un  
système de gestion de la qualité certifié selon la  
norme |  
We as manufacturer operate under a certified quality  
management system according to

DIN EN ISO 13485:2021-12.

Bad Kissingen, 2025-JAN-03

Florian Dassel

Directeur et personne responsable (évaluation de la conformité) |  
Managing Director and Person Responsible for Regulatory Compliance (Conformity Assessment)

# Declaração de conformidade | Declaration of Conformity

Nós, enquanto fabricante |  
We as manufacturer

Geratherm Respiratory GmbH  
Kasernenstraße 4  
97688 Bad Kissingen  
Alemanha | Germany  
EUDAMED SRN: DE-MF-000006818  
DE-PR-000020481

## Spirostik Blue

Utilização prevista: Dispositivo para determinar volumes pulmonares  
estáticos e dinâmicos |

Intended use: Device for determining static and dynamic lung volumes

declaramos sob nossa exclusiva responsabilidade  
que o produto |  
declare under sole responsibility that the product

REF: 356246 (anterior | old REF: 40.070)  
UDI-DI: 04065803002008

Número de série (année de production) | Serial number (year of production):  
de | from 2111xxxxx (2025) a | to 2111xxxxx (2026)

Versão TD | TD version: 1.0.5.2

Basis | Basic UDI-DI:

065803002GR01ACNK

EMDN:

Z12150101

UMDNS:

13-674

MDR Code:

MDA 0204

a que se refere a presente declaração, |  
to which this declaration relates,

de acordo com a Regra 10 do Anexo VIII do  
Regulamento (UE) 2017/745 (MDR), o produto está  
classificado como |  
according to Rule 10 of Annex VIII of Regulation  
(EU) 2017/745 (MDR) the product is classified as

Dispositivo médico da classe de risco | Medical Device of risk  
class  
**Ila,**

é fabricado, lançado e colocado no mercado nos  
termos do  
is manufactured, released, and placed on the market  
under

Regulamento (UE) 2017/745 (MDR) |  
Regulation (EU) 2017/745 (MDR)

e está em conformidade com os requisitos da |  
and complies with the requirements according to

Directiva | Directive 2011/65/EU (RoHS).

O produto foi aprovado num procedimento de  
avaliação da conformidade de acordo com |  
The product successfully passed a conformity  
assessment procedure according to

Anexo IX, Capítulo 1, do Regulamento (UE) 2017/745 (MDR) |  
Annex IX, Chapter 1 of the Regulation (EU) 2017/745 (MDR)

e é rotulado com a marca de conformidade |  
and is labeled with the conformity mark

**CE** 0494

Organismo notificado: |  
Notified Body:

SLG Prüf- und Zertifizierungs GmbH  
Burgstädter Straße 20  
09232 Hartmannsdorf  
Alemanha | Germany

Nós, enquanto fabricantes, operamos com um  
sistema de gestão da qualidade certificado de  
acordo com a norma |  
We as manufacturer operate under a certified quality  
management system according to

DIN EN ISO 13485:2021-12.

Bad Kissingen, 2025-JAN-03

**Florian Dassel**

Director-Geral e Responsável pela Conformidade Regulamentar (Avaliação da Conformidade) |  
Managing Director and Person Responsible for Regulatory Compliance (Conformity Assessment)

# Uygunluk beyanı | Declaration of Conformity

Biz üretici olarak |  
We as manufacturer

Geratherm Respiratory GmbH  
Kasernenstraße 4  
97688 Bad Kissingen  
Almanya | Germany  
EUDAMED SRN: DE-MF-000006818  
DE-PR-000020481

## Spirostik Blue

Kullanım amacı: Statik ve dinamik akciğer hacimlerini belirleyen cihaz |  
Intended use: Device for determining static and dynamic lung volumes

ürününün tek sorumluluk altında olduğunu beyan eder |  
declare under sole responsibility that the product

REF: 356246 (eski | old REF: 40.070)

UDI-DI: 04065803002008

Seri numarası (üretim yılı) | Serial number (year of production):  
den | from 2111xxxxx (2025) e kadar | to 2111xxxxx (2026)

TD versiyon | TD version: 1.0.5.2

Basis | Basic UDI-DI:

065803002GR01ACNK

EMDN:

Z12150101

UMDNS:

13-674

MDR Code:

MDA 0204

bu beyanın ilgili olduğu, |  
to which this declaration relates,

2017/745 (EU) sayılı (MDR) yönetmeliği EK VIII  
Kural 10' a göre ürün şu şekilde sınıflandırılır |  
according to Rule 10 of Annex VIII of Regulation  
(EU) 2017/745 (MDR) the product is classified as

**Tıbbi Cihaz risk sınıfı | Medical Device of risk class  
IIa,**

göre üretilmekte, piyasa sürülmekte ve piyasaya arz  
edilmektedir. |  
is manufactured, released, and placed on the market  
under

Yönetmelik (EU) 2017/745 (MDR)  
Regulation (EU) 2017/745 (MDR)

göre belirtilen gerekliliklere uygundur |  
and complies with the requirements according to

2011/65/EU sayılı Direktif (RoHS) | Directive 2011/65/EU (RoHS).

Ürün, belirtilenlere göre bir uygunluk değerlendirme  
prosedürünü başarıyla geçmiştir |  
The product successfully passed a conformity  
assessment procedure according to

Ek IX, 2017/745 (EU) sayılı Tüzük Bölüm 1 (MDR) |  
Annex IX, Chapter 1 of the Regulation (EU) 2017/745 (MDR)

ve uygunluk işareti ile işaretlenmiştir |  
and is labeled with the conformity mark

**CE** 0494

Onaylanmış kuruluş: |  
Notified Body:

SLG Prüf- und Zertifizierungs GmbH  
Burgstädter Straße 20  
09232 Hartmannsdorf  
Almanya | Germany

Biz üretici olarak, sertifikalı bir kalite yönetim sistemi  
altında faaliyet gösteriyoruz |  
As a manufacturer, we operate under a certified  
quality management system according to

DIN EN ISO 13485:2021-12.

Bad Kissingen, 2025-JAN-03

**Florian Dassel**

Genel Müdür ve Mevzuata Uygunluktan Sorumlu Kişi (Uygunluk Değerlendirmesi) |  
Managing Director and Person Responsible for Regulatory Compliance (Conformity Assessment)