EC Certificate Production Quality Assurance System FI18/07004

The management system of

Spiromagic ApS

Dynamovej 11, 2.TV
2860 Søborg
Denmark

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on Medical Devices, Annex V

For the following products

Spirometers

Products covered are listed in Attachment 1 of this certificate

This certificate is valid from 20 April 2018 until 20 April 2023
and remains valid subject to satisfactory surveillance audits.
Recertification audit due before 20 April 2021
Issue 1. Certified since 20 April 2018
This certification is based on decision: FI18/07004P0

Authorised by

Tom Törn, Certification Director
SGS Fimko Ltd., Notified Body 0598

Attachment 1 to SGS Fimko Ltd. EC certificate FI18/07004 Issue 1

Manufacturer	Spiromagic ApS
Address	Dynamovej 11, 2.TV, 2860 Søborg, Denmark
Activity and Product Category	93/42/EEC Annex V Spirometers

List of product names and the corresponding product type/model markings with trademarks/marketing names covered by this certificate:

Product Name	Class	Model/type nr. and Trademark(s)
Spirometers	IIa	Spiromagic Spirometer

Authorised by

Tom Törn, Certification Director
SGS Fimko Ltd., Notified Body 0598

Issue 1
Date issued/revised: 20.04.2018

20 April 2018 FI18/07004P0

Spiromagic ApS
Dynamovej 11, 2.TV
2860 Søborg
Denmark

EC-certification application 18.11.2016

Subject	Certification of quality system and product range, based on Council Directive 93/42/EEC concerning medical devices, Annex V Section 3.
Manufacturer	Spiromagic ApS Dynamovej 11, 2.TV 2860 Søborg Denmark
Decision	A certificate will be issued for the manufacturer. The certificate covers the following products:

Product	**Model**	**Class**
Spirometer	Spiromagic Spirometer	IIa

Justification	SGS Fimko Ltd has assessed manufacturer's quality management system and products. Quality management system and products meet the requirements of Annex V of Medical Device Directive 93/42/EEC. The decision is based on audit report 285912 and recommendation of technical review. The manufacturer has signed the undertaking to follow the obligations of Annex V and Annex VII of the Directive.
Certificate related to decision	FI18/07004 Issue 1
Valid until	This decision is valid until 20.04.2023 providing the requirements of the certification are fulfilled.
Date	Helsinki, 20.04.2018

Tom Törn, Certification Director
SGS Fimko Ltd, Notified Body 0598