

## DECLARATION OF CONFORMITY

<b>Manufacturer's Name</b>	İnofab Sağlık Teknolojileri Anonim Şirketi
<b>Trade Mark</b>	Spirohome®
<b>Head Office</b>	Üniversiteler Mah. İhsan Doğramacı Blv. No:19 Çankaya / Ankara / Türkiye 06800
<b>Production/Warehouse</b>	Üniversiteler Mah. İhsan Doğramacı Blv. No:29 Çankaya / Ankara / Türkiye 06800
<b>Product Name</b>	Spirohome Ultrasonic Spirometer
<b>Product Description</b>	Spirometry System
<b>Classification</b>	Class IIa (rule 10)
<b>Product GMDN</b>	#35282
<b>Accessory</b>	Mouthpiece
<b>Accessory Description</b>	Spirometry System
<b>Classification</b>	Class IIa (rule 5)
<b>Accessory GMDN</b>	#43467 (reusable mouthpiece) #44545 (disposable mouthpiece)

Product Name	Variant	Sizes	GMDN	Class
Spirohome Ultrasonic Spirometer	01- Personal Use	01- 110 x 63,3 x 40,8 mm	35282	IIa
	02- Clinic Use	02- 110 x 63,3 x 40,8 mm		
Spiroway Mouthpiece	01- Reusable Mouthpiece	01- 109.2 x 49.6 x 28.5 mm	43467	IIa
	02- Disposable Mouthpiece	02- 109.2 x 49.6 x 28.5 mm	44545	
Product Name		Barcode Number		
Spirohome® Personal		8682084050007		
Spirohome® Clinic		8682084050014		
Spiroway® Resuable Mouthpiece		8682084050021		
Spiroway® Disposable Mouthpiece		8682084050038		

We herewith declare that the above mentioned products meet the provisions of the medical devices directive 93/42/EEC (with the latter amendments of this directive) for medical devices and is in compliance with the radio equipment directive 2014/53/EU. All supporting documentation is retained under the premises of the manufacturer.

İnofab Sağlık Teknolojileri A.Ş.

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# inofab health

<b>Conformity Assessment Route</b>	MDD 93/42/EEC, Annex II Section 3 RED 2014/53/EU
<b>Notified Body</b>	KIWA Belgelendirme Hizmetleri A.Ş. ITOSB 9. Cadde No:15 Tepeören - İstanbul / Turkey
<b>Notified Body Identification Number</b>	1984
<b>Applicable Standard(s)</b>	EN 60601-1: 2009 EN 60601-1-11 :2015 EN 60601-1-2: 2016 EN 62304:2006/A1 EN ISO 26782:2009 /AC:2009 EN ISO 23747: 2009 ETSI EN 300 328 V2.1.1 ETSI EN 301 489-1 V2.2.0 ETSI EN 301 489-17 V3.2.0
<b>Start of CE-marking</b>	11.02.2019
<b>Place of Issue</b>	Üniversiteler Mah. İhsan Doğramacı Blv. No:19 Çankaya / Ankara
<b>Date of Issue</b>	03.05.2019

**Authorized Name, Title  
Stamp-Signature**

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