

DECLARATION OF CONFORMITY

Manufacturer: Inofab Sağlık Teknolojileri Anonim Şirketi
Trade Mark: Spirohometm[®]
Address: Üniversiteler Mah. İhsan Doğramacı Blv. No:19 Çankaya – Ankara / TURKEY
Product: Spirohometm Ultrasonic Spirometer
Product Designation: Spirometry System
Classification: Class IIa (Rule 10)
Product Group: #35282 (Spirometer)
Accessory: Mouthpiece
Accessory Designation: Spirometry System
Classification: Class IIa (Rule 5)
Product Group: #43467 (Reusable Mouthpiece)
#44545 (Disposable Mouthpiece)

Name of Product	Variant	Sizes	GMDN	Class
Spirohometm Ultrasonic Spirometer	01-Personal Use 02-Clinic Use	01- 110 x 63,3 x 40,8 mm 02- 110 x 63,3 x 40,8 mm	35282	IIa
Spiroway Mouthpiece	01- Reusable Mouthpiece 02- Disposable Mouthpiece	01- 109.2 x 49.6 x 28.5 mm 02- 109.2 x 49.6 x 28.5 mm	43467 44545	IIa

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.

Conformity Assessment Route: MDD 93/42/EEC, Annex II Section 3
RED 2014/53/EU

Notified Body: KIWA Belgelendirme Hizmetleri A.Ş.
ITOSB 9. Cadde No:15 Tepeören – İstanbul / Turkey

Notified Body Identification Number: 1984

Applicable Standard(S):

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

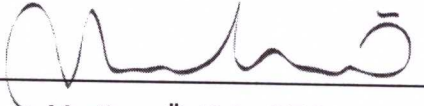
Start of CE Marking:

11.02.2019

Place, Date of Issue:

Üniversiteler Mah. İhsan Doğramacı Blv. No:19 Çankaya / Ankara /
Turkey, 11.02.2019

Signature:


Merthan Öztürk, CEO