

# ***FLO-DOC0012***

## ***SpiroSonic Flo EC***

### ***Declaration of Conformity***

Revision: 10.0

#### **Revision history**

Document status: D - Draft, R - Revised, A - Approved

<b>Rev.</b>	<b>Author</b>	<b>Date</b>	<b>Status</b>	<b>Comment</b>
10.0	Szabolcs Reichardt	2019-08-01	R,A	Added: Directive 93/42/EEC on Medical devices, Annex II excluding (4)

Filename: FLO-DOC0012 - SpiroSonic Flo EC Declaration of Conformity  
Created by: Attila Szakadati (2014-01-17)  
Last revision by: Szabolcs Reichardt (2019-08-01)  
Last approval by: Szabolcs Reichardt (2019-08-01)

# CE 2409

## EC Declaration of Conformity

---

**Manufacturer**

Uscom Kft.  
Boglarka street 17., Budapest 1119, Hungary

---

**Description of the device**

PC Spirometer

---

**Type**

SpiroSonic Flo

---

**Classification**

Class IIa  
Council Directive 93/42/EEC of MDD as amended by Directive 2007/47/EC, Annex IX, rule 10,  
Directive 93/42/EEC on Medical devices, Annex II excluding (4)

---

**Declaration**

We hereby declare that the above listed product complies with the provisions of the Council Directive 93/42/EEC as amended by Directive 2007/47/EC for medical devices. All supporting documentation is retained under the premises of the manufacturer.

---

**Applied standards**

MSZ EN 60601-1:2017	MSZ EN ISO 15223-1:2017
MSZ EN 60601-1-2:2016	MSZ EN 1041:2008+A1:2014
MSZ EN 60601-1-6:2010/A1:2015	MSZ EN ISO 14971:2013
MSZ EN 62366-1:2015	MSZ EN ISO 26782:2009
MSZ EN 62304:2006	MSZ EN ISO 10993-1:2010

---

**Notified Body:**

CE Certiso Ltd., Organization for Certification and Testing on the Field of Medical and Hospital Engineering  
H-2040 Budaörs, Gyár u. 2. BITEP, Gábor Dénes krt. 101.

---

**EC Certificates:**

Directive 93/42/EEC	144759-18-06-18
MSZ EN ISO 13485:2016	144747-18-04-08
MSZ EN ISO 9001:2015	144746-18-04-08

---

Budapest, 2019-08-01

**Uscom Kft.**  
1119 Budapest, Boglárka u. 17.  
Adószám: 24083559-2-43  
Cégsz.: 01-09-329610  
  
Szabolcs Reichardt  
Quality Assurance Manager

# SR-DOC0012

# *SpiroReporter Software EC Declaration of Conformity*

Revision: 9.0

## Revision history

Document status: D - Draft, R - Revised, A - Approved

Rev.	Author	Date	Status	Comment
1.0	Attila Szakadati	2014-01-17	D	Initial revision.
2.0	BalazsHerczeg	2015-02-02	R	Address has been changed.
3.0	BalazsHerczeg	2015-04-10	R	Notified Body has been changed.
4.0	BalazsHerczeg	2016-02-17	R	Notified Body has been changed.
5.0	BalazsHerczeg	2016-06-20	R	New DocID and modified document style.
6.0	Szabolcs Reichardt	2018-01-10	R, A	MSZ EN ISO 13485 and 9001 changed
7.0	Szabolcs Reichardt	2018-06-19	R,A	New EC Certificate numbers
8.0	Szabolcs Reichardt	2018-09-27	R,A	Manufacturer's name has been changed
9.0	Szabolcs Reichardt	2019-01-02	R,A	Address and 60601 Standards have been changed

Filename: SR-DOC0012 - SpiroReporter EC Declaration of Conformity

Created by: Attila Szakadati(2014-01-17)

Last revision by: Szabolcs Reichardt (2019-01-02)

Last approval by: Szabolcs Reichardt (2019-01-02)

# CE 2409

## EC Declaration of Conformity

---

**Manufacturer**

UscomKft.  
Boglarka street 17., Budapest 1119, Hungary

---

**Description of the device**

PC Software

---

**Type**

SpiroReporter Software

---

**Classification**

Class IIa  
Council Directive 93/42/EEC of MDD as amended by Directive 2007/47/EC, Annex IX, rule 10

---

**Declaration**

We hereby declare that the above listed product complies with the provisions of the Council Directive 93/42/EEC as amended by Directive 2007/47/EC for medical devices. All supporting documentation is retained under the premises of the manufacturer.

---

**Applied standards**

MSZ EN 60601-1:2017	MSZ EN ISO 15223-1:2017
MSZ EN 60601-1-2:2016	MSZ EN 1041:2008+A1:2014
MSZ EN 60601-1-6:2010/A1:2015	MSZ EN ISO 14971:2013
MSZ EN 62366-1:2015	MSZ EN ISO 26782:2009
MSZ EN 62304:2006	MSZ EN ISO 10993-1:2010

---

**Notified Body:**

CE Certiso Ltd., Organization for Certification and Testing on the Field of Medical and Hospital Engineering  
H-2040 Budaörs, Gyár u. 2. BITEP, GáborDéneskr. 101.

---

**EC Certificates:**

Directive 93/42/EEC	144759-18-06-18
MSZ EN ISO 13485:2016	144747-18-04-08
MSZ EN ISO 9001:2015	144746-18-04-08

---

Budapest, 2019-01-02

**Uscom Kft.**  
1119 Budapest, Boglárka u. 17.  
Adószám: 24083559-2-43  
Cégl.sz.: 01-09-339610  
  
**Szabolcs Reichardt**  
Quality Assurance Manager