

# ***ST-DOC0012***

# ***SpiroTube PC 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	2019-03-11	R,A	New stamp

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Created by: Attila Szakadati (2014-01-17)  
Last revision by: Szabolcs Reichardt (2019-03-11)  
Last approval by: Szabolcs Reichardt (2019-03-11)

# CE 2409

## EC Declaration of Conformity

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**Manufacturer**

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

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**Description of the device**

PC Spirometer

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**Type**

SpiroTube PC

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**Classification**

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

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**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.

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**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

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**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.

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**EC Certificates:**

Directive 93/42/EEC	144758-18-06-18
MSZ EN ISO 13485:2016	144747-18-04-08
MSZ EN ISO 9001:2015	144746-18-04-08

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Budapest, 2019-03-11

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