OTH-DOC0012

OTTHON EC Declaration of Conformity

Revision: 7.0

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	Balazs Herczeg	2015-02-02	R	Address has been changed.
3.0	Balazs Herczeg	2015-04-10	R	Notified Body has been changed.
4.0	Balazs Herczeg	2016-02-17	R	Notified Body has been changed.
5.0	Balazs Herczeg	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 certificates numbers

Filename: OTH-DOC0012 - OTTHON EC Declaration of Conformity.docx
Created by: Attila Szakadati (2014-01-17)
Last revision by: Szabolcs Reichardt (2018-06-19)
Last approval by: Szabolcs Reichardt (2018-06-19)

CE 2409

EC Declaration of Conformity

Manufacturer

THOR Laboratories Kft.
Pajkos street 50., Budapest 1119, Hungary

Description of the device

Mobile Handheld Spirometer

Type

OTTHON

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 60601-1:2006/A1:2014	MSZ EN ISO 15223-1:2017
EN 60601-1-2:2007/AC:2010	MSZ EN 1041:2008+A1:2017
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	144758-18-06-18
MSZ EN ISO 13485:2016	144747-18-04-08
MSZ EN ISO 9001:2015	144746-18-04-08

Budapest, 2018-06-19

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Cégjegyzékszám: 07-09-022749

Szabolcs Reichardt

Quality Assurance Manager