

DECLARATION OF CONFORMITY

1) **Manufacturer:** Worldwide Innovations & Technologies, Inc.

Address: 2834 Roe Lane, Kansas City, Kansas 66103 USA

2) **European authorized representative:** QNET B.V.

Address: Hommerterweg 286, 6436 AM, Amstenrade, The Netherlands;

on product labels printed as:



QNET BV
Hommerterweg 286
6436 AM Amstenrade
The Netherlands

3) **Product(s)**

Non-sterile radiation-protective surgical drapes and shields. See attached appendix.

4) **The product(s) described above is in conformity with:**

<u>Document No.</u>	<u>Title</u>	<u>Edition / Date of issue</u>
L 169; 93/42/EEC	Medical Device Directive	1993-06-14

5) **Additional information:**

Risk Class 1

Risk Rule 1

The following standards have either been referred to or been complied with in part or in full as relevant:

ISO 13485:2003

EN ISO 14971:2012

EN 15223-1:2012

EN 1041:2008

6) **Date of first CE Marking:** 30 June 2010

February 15, 2013

(Date of Issue)

Kansas City, Kansas

Catherine W. Cadwalader

(Signature of manufacturer)

Catherine W. Cadwalader, President and CEO

18 February 2013 
(Date) Drs. A.H.G.M. Denissen, QNET B.V.
(name; function and signature of authorized representative)

APPENDIX

List of Devices:

UMDNS Code	TYPE/MODEL/NUMBER	FIRST DATE OF CE MARKING
16006	Drapes, Angiographic	30 June 2010
12368	Drapes, Surgical	30 June 2010
15646	Drapes, Surgical, Disposable	30 June 2010
14490	Shields, X-ray	30 June 2010