

## DECLARATION OF CONFORMITY

1) Manufacturer: **Dotolo Research Corporation**

Address: **10199 W. Van Buren Street, Suite 10, Tolleson, Arizona 85353 USA**

and

2) European authorized representative: **CEpartner4U BV,**

Address: **Esdoornlaan 13, 3951DB Maarn. The Netherlands;**

(on product labels printed as:

CEpartner4U , Esdoornlaan 13, 3951DB Maarn. The Netherlands. Tel.: +31 (0)6.516.536.26;

or as: CEpartner4U, 3951DB; 13. NL. tel: +31 (0)6.516.536.26)

3) Product(s) (name, type or model/batch number, first year of registration.):

**Toxygen BSCUV Colon Hydrotherapy Systems with accessories  
and disposable packs**

4) The product(s) described above are 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 (conformity procedure, Notified Body, CE certificate, etc.)

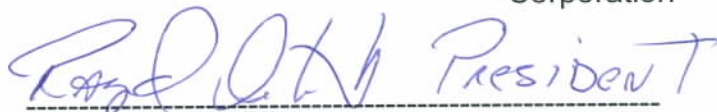
Conformity assessment procedure for CE marking:

Class IIa devices: Medical Device Directive, Annex II (excluding section 4).

Notified Body: Nemko, NB No. 0470, Approval of Conformity: certificate Nr. EU0109007

Dotolo Research Corporation  
Pinellas Park, Florida

Ray Dotolo, President/CEO Dotolo Research  
Corporation

 President

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(Place & date of issue in USA)

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(name, function and signature of manufacturer)

Maarn, NL

Harry Teirlinck, Senior Consultant, CEpartner4U BV

----- 2004-07-06 -----

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(Place & date of issue)

(name; function and signature of authorized representative)

## Appendix A

Date: 2004-07-06

### List of products.

<b>Device</b>	<b>Risk class/rule</b>	<b>First CE-marking</b>
Toxygen Model BSC-UV	Risk class IIa, rule 11	2001-05-11
Toxygen Model BSC-UV Accessory Pack	Risk class IIa, rule 11	2001-05-11
Colon Hydrotherapy Disposable Packs 48"SB/ Cuffed	Risk class IIa, rule 5	2001-05-11
Colon Hydrotherapy Disposable Packs 42"	Risk class IIa, rule 5	2001-05-11
Colon Hydrotherapy Disposable Speculum / Obturator	Risk class IIa, rule 5	2001-05-11