

DECLARATION OF CONFORMITY

1) **Manufacturer** *(Name, department):* **Pos-T-Vac, Inc.**

Address: **2111 West Wyatt Earp Blvd., Dodge City, KS 67801, 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. www.cepartner4u.eu)

3) **Product(s)** *(name, type or model/batch number, etc.):*

Constriction Therapy Device – Constriction Rings – Auto Injector – Continence Clamp
see appendix

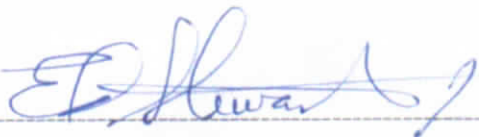
4) **The product(s) described above is in conformity with:**

Title	Document No.
Medical Device Directive	93/42/EEC

5) **Additional information** *(conformity procedure, Notified Body, CE certificate, Registration nr., etc.):*

Conformity assessment procedure for CE marking: Medical Device Directive, Annex VII
Registration nr.: **NL-CA002-2012-24773**

Dodge City, USA; 2016-06-17



Ed Stewart, Jr., President, Pos-T-Vac, Inc.

(Place & date of issue (yyyy-mm-dd)) (name, function and signature of manufacturer)

Appendix

Date: 2016-06-17

List of devices.

Device name	Type/ model/ref number	Risk class / rule ¹	First date of CE-compliance
Constriction Therapy Device	- IVP-600, - AVP-1000, - MVP-700	Class I / rule 1 Non Sterile	1998-10-08
Constriction Therapy Device	- BOSS-2000-2 - BOSS-2000-3 -Rejoyn -Androvacuum	Class I / rule 12 Non Sterile	2002-06-11 2002-06-11 2016-06-15 2011-05-07
Constrictor Rings	- B-series, - B-100, - B-25, - B-10	Class I / rule 1 Non Sterile	1998-10-08
Incontinence Clamp	- Clamp	Class I / rule 1 Non Sterile	2000-06-07

¹ See risk classification in Medical Device Directive, annex IX

To: Pos-T-Vac, Inc.
Dodge City, USA

Maarn, The Netherlands, 2016-05-20

Subject: Authorized representative contract ARMD1998-01-05
Amendment letter – Exhibit D

Dear Dennis,

Due to the Address change of Pos-T-Vac, Inc.

Old Address (Agreement):

P.O. Box 1436, 1701 N. 14th Avenue, Dodge City, Kansas 67801

New Address:

2111 W. Wyatt Earp, Dodge City, KS, 67801, USA

we add to the original authorized representative agreement ARMD1998-01-05 this
letter ARMD1998-01-05 Exhibit D.

We present this signed original for this purpose, kindly print and co-sign two copies
and return one to us for our files.

Your cooperation is most appreciated,

Sincerely,

Signatures:

CEpartner4U B.V.:

By: 
Mr. Ton Pennings

Its: Director

Date (yyyy-mm-dd): 2016-05-20

Manufacturer:

By: 
Ed Stewart

Its: CEO

Date (yyyy-mm-dd): 2016-05-20