

A medical appliance is an item that directly substitutes for a malfunctioning part of the human body. Products that qualify as medical appliances are taxed at a lower State rate of 1% plus any applicable local taxes. See 86 Ill. Adm. Code 130.311. (This is a PLR).

December 21, 2015

Dear Mr. Xxxxx:

This letter is in response to your letter dated November 12, 2015, in which you request information. The Department issues two types of letter rulings. Private Letter Rulings (“PLRs”) are issued by the Department in response to specific taxpayer inquiries concerning the application of a tax statute or rule to a particular fact situation. A PLR is binding on the Department, but only as to the taxpayer who is the subject of the request for ruling and only to the extent the facts recited in the PLR are correct and complete. Persons seeking PLRs must comply with the procedures for PLRs found in the Department’s regulations at 2 Ill. Adm. Code 1200.110. The purpose of a General Information Letter (“GIL”) is to direct taxpayers to Department regulations or other sources of information regarding the topic about which they have inquired. A GIL is not a statement of Department policy and is not binding on the Department. See 2 Ill. Adm. Code 1200.120. You may access our website at [www.tax.illinois.gov](http://www.tax.illinois.gov) to review regulations, letter rulings and other types of information relevant to your inquiry.

Review of your request disclosed that all the information described in paragraphs 1 through 8 of Section 1200.110 appears to be contained in your request. This Private Letter Ruling will bind the Department only with respect to ABC for the issue or issues presented in this ruling, and is subject to the provisions of subsection (e) of Section 1200.110 governing expiration of Private Letter Rulings. Issuance of this ruling is conditioned upon the understanding that neither ABC nor a related taxpayer is currently under audit or involved in litigation concerning the issues that are the subject of this ruling request. In your letter you have stated and made inquiry as follows:

Please accept this letter as our official request for a Private Ruling Letter regarding the sales and use taxability and tax rate of our product the PRODUCT.

To the best of the knowledge of ABC (‘ABC’): (1) the Illinois Department of Revenue (‘Department’) has not previously ruled on the same or similar issue for ABC; (2) the same or similar issue was not previously submitted and withdrawn by ABC prior to the Department’s issuance of a PLR; and (3) ABC is not under audit by or involved in litigation with the Department.

## **FACTS**

The PRODUCT (please see enclosed Exhibit) is designed to correct a physical deformity in the male urinary tract known as Benign Prostatic Hyperplasia (“BPH”). BPH involves hyperplasia (an increase in the number of cells) of certain cells in the prostate gland that surrounds the urethra. This increase in cells results in the formation of large nodules in the transition zone of the prostate. When sufficiently large, the nodules deform the urethra and increase resistance to flow of urine from the bladder.

The PRODUCT corrects this deformation with permanent adjustable transprostatic implants placed by a health care provider during a cystourethroscopy. Each permanent adjustable transprostatic implant is sold to hospital or medical facilities in its own sterile, individual housing, which is designed to couple to a urethroscope.<sup>1</sup> The housing is single use; it is not reloadable or reusable.

The housing includes a handle for positioning the implant and coupling to the urethroscope, a retractable needle for puncturing the capsule of the prostate gland, and a tensioning spring within the handle for allowing adjustment of the implant during placement. The PRODUCT transprostatic implant is a permanent implant made up of standard surgical implantable materials: a nitinol capsular tab, a stainless steel urethral tab, and polyester suture that connects the two tabs.

Together, the permanent adjustable transprostatic implant and its housing form the PRODUCT for which this request is made. As discussed above, the PRODUCT is sold to hospitals or medical facilities to correct a physical deformity and must be prescribed by a physician.

The implant and its housing are sold together as an indivisible unit. The urethroscope is sold separately and is not included in the PRODUCT. The Food & Drug Administration cleared the implant and housing to be used together as an indivisible unit. The Centers for Medicare & Medicaid Services (“CMS”) reimburse the placement of the implant and housing as an indivisible unit under a single procedure code (Current Procedural Terminology Code or CPT Code 52441), which describes the procedure using the PRODUCT as “cystourethroscopy, with insertion of permanent adjustable transprostatic implant.” Finally, health care providers have been reimbursed by CMS for the use of the PRODUCT under the CMS Healthcare Common Procedure Coding System Product Code L8699, which has the description “Prosthetic implant, not otherwise specified.” These reimbursements under the prosthesis description were applied to the implant and housing as an indivisible unit.

## **LAW AND ANALYSIS**

Under 35 ILCS 120/2-10, unless otherwise provided in this Section, the tax imposed by this Act is at the rate of 6.25% of gross receipts from sales of tangible personal property made in the course of business.

With respect to....prescription and non-prescription medicines, drugs, medical appliances...for human use, the tax is imposed at a rate of 1%.

Under 86ILAC 130.311(a), General.

With respect to prescription and non-prescription medicines, drugs, medical appliances...for human use, the tax is imposed at the rate of 1%.

Under 86ILAC 130.311(d) *Medical Appliances*: A medical appliance is an item that is used to directly substitute for a malfunctioning part of the human body.

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<sup>1</sup> This letter addresses only the exemption for the PRODUCT and not the urethroscope, which is sold separately and is not within the scope of this request for private letter ruling.

- (1) For purposes of this Section, an item that becomes part of the human body by substituting for any part of the body this is lost or diminished because of congenital defects, trauma, infection, tumors or disease is considered a medical appliance. Examples of medical appliances that will qualify the product for the low rate of tax include, but are not limited to:
  - (A) Breast implants that restore breasts after loss due to cancer;
  - (B) Heart pacemakers;
  - (C) Artificial limbs;
  - (D) Dental prosthetics;
  - (E) Crutches and orthopedic braces;
  - (F) Dialysis machines (including the dialyzer);
  - (G) Wheelchairs; and
  - (H) Mastectomy forms and bras
  
- (7) Medical appliances may be prescribed by licensed health care professionals for use by a patient, purchased by health care professionals for the use of patients or purchased directly by individuals.

Under ST 11-0064-GIL (08.16.2011), the Department provided valuable information regarding medical appliances. There were several products and service offerings in question for which the Department gave a response to the taxability and rate in the General Information Letter.

1. The Prosthetic Device (category 1) – devices worn on or in the patient to replace or assist in the functioning of the human heart. The devices were either implantable or paracorporeal (attached to the patient at all times). They were sold or provided to the taxpayer either directly through hospitals or prescribed by licensed physicians for the treatment of patients and dispensed accordingly.

These category 1 prosthetic devices were subject to Illinois sales and use tax rates (ROT, SOT, SUT and UT) at a reduced rate when sold in Illinois because they were considered qualifying medical appliances.

2. External Component of Prosthetic Devices (category 2) – external components of the prosthetic devices that, together with the internal device, work interdependently as one device to assist in the functioning of the heart.

These category 2 external components to prosthetic devices were subject to Illinois sales and use tax rates (ROT, SOT, SUT and UT) at a reduced rate when sold in Illinois because they were considered qualifying medical appliances.

3. Supplies of Prosthetic Devices (category 5)– certain supplies assisted with the functionality of the prosthetic device and included vests/holsters, shower kits, rapid charger stations

These category 5 supplies needed further clarification in order to rule on the reduced taxable rate of 1%. The Department noted that supplies that are akin

to “accessories” that are “necessary for the operation of a qualifying medical appliance qualify for the lower rate of tax. However, these part [sic] and accessories must be integral to the operation of the medical appliance”.

We believe the PRODUCT meets all the requirements for an IL sales and use reduced tax rate of 1%, pursuant to:

1. 35 ILCS 120/2-10 and 86ILAC 130.311(a), the PRODUCT is prescribed medical appliance for human use and should be taxed at a reduced rate of 1%.
2. 86ILAC 130.311(d)(1),(7), the PRODUCT is a medical device implanted in the body and designed to substitute for a physical deformity to the male urinary tract which an illness called Benign Prostatic Hyperplasia (“BPH”). The PRODUCT is sold to an individual by prescription for use by the individual.
3. ST 11-0064-GIL (08.16.2011), the PRODUCT should, in our opinion, be viewed as one indivisible unit (implant and housing). It is currently being billed as one single procedure code - CPT Code 52441, which describes the procedure using the PRODUCT as “cystourethroscopy, with insertion of permanent adjustable transprostatic implant.” As well, health care providers have been reimbursed by CMS for the use of the PRODUCT under the CMS Healthcare Common Procedure Coding System Product Code L8699, which has the description “Prosthetic implant, not otherwise specified.” These reimbursements under the prosthesis description were applied to the implant and housing as an indivisible unit.

In applying the analysis of ST 11-0064-GIL (08.16.2011), the PRODUCT as a whole, could be taxed at the reduced rate of 1% for the entire unit as being defined as a prosthetic device. We also believe that the PRODUCT could also be viewed as a prosthetic devices [sic] (implant) and accessories (supplies) to the prosthetic devices (housing) that are absolutely necessary for the operation of the qualifying prosthetic and integral to the operation of the medical appliance. Either way, we believe the reduced tax rate of 1% would apply.

While the PRODUCT is a new and innovative prosthetic device and has created a category of prosthesis not previously available to Illinois hospitals or medical facilities, the PRODUCT is comparable to other recognized prostheses and medical devices and equipment such as implantable cardio- defibrillators (“ICD”), pacemakers, orthopedic and spinal implants, insulin infusion devices, stents, surgical mesh, artificial hearts valves, penile implants and artificial limbs. As such, we believe the PRODUCT meets the definition of either or both a “prosthetic device” and “supplies” and is exempt from sales tax.

## **REQUEST FOR RULING**

We respectfully request confirmation that the sale of the PRODUCT meets the statutory definition of a sales and use tax exempt prosthetic device pursuant to 35 ILCS 120/2-10, 86ILAC 130.311(a), 86ILAC 130.311(d)(1),(7) and ST 11-0064-GIL (08.16.2011).

Should you have any questions or require additional information, please contact me at (XX) XXX-XXX or by email.

Thank you for prompt consideration of this matter.

#### **DEPARTMENT'S RESPONSE:**

The Department's regulation regarding the appropriate tax rate for medical appliances can be found at 86 Ill. Adm. Code 130.311. Products that qualify as medical appliances are taxed at the lower State rate of 1% plus any applicable local taxes. Those items that do not qualify for the lower rate of tax are taxed at the general merchandise rate of 6.25% plus any applicable local taxes.

A medical appliance is an item that directly substitutes for a malfunctioning part of the human body. Medical appliances may be prescribed by licensed health care professionals for use by a patient, purchased by health care professionals for the use of patients, or purchased directly by individuals. See 86 Ill. Adm. Code 130.311(d)(7). Please note that not all items prescribed by or used by physicians or other licensed health care professionals qualify for the reduced rate.

Medical appliances that qualify for the reduced rate include such items as artificial limbs, dental prostheses and orthodontic braces, crutches and orthopedic braces, wheelchairs, heart pacemakers, and dialysis machines. Other examples of items that qualify for the reduced rate are corrective medical appliances such as hearing aids, eyeglasses and contact lenses. As a general proposition, diagnostic, treatment, and rehabilitative equipment do not qualify for the reduced rate of tax as medical appliances because such items are not "for use in directly substituting for a malfunctioning part of the body," 86 Ill. Adm. Code 130.311(d).

Based upon the information contained in your letter and in the accompanying literature, as well as the description of the way the PRODUCT works, it is the Department's position that the PRODUCT qualifies as a medical appliance and should be taxed at the lower State rate of 1% plus any applicable local taxes.

The factual representations upon which this ruling is based are subject to review by the Department during the course of any audit, investigation, or hearing and this ruling shall bind the Department only if the factual representations recited in this ruling are correct and complete. This Private Letter Ruling is revoked and will cease to bind the Department 10 years after the date of this letter under the provisions of 2 Ill. Adm. Code 1200.110(e) or earlier if there is a pertinent change in statutory law, case law, rules or in the factual representations recited in this ruling.

I hope this information is helpful. If you have questions concerning this Private Letter Ruling, you may contact me at (217) 782-2844. If you have further questions related to the Illinois sales tax laws, please visit our website at [www.tax.illinois.gov](http://www.tax.illinois.gov) or contact the Department's Taxpayer Information Division at (217) 782-3336.

Very truly yours,

Richard S. Wolters  
Chairman, Private Letter Ruling Committee

RSW:DMB