



## North Carolina Department of Revenue

Roy Cooper  
Governor

Ronald G. Penny  
Secretary

October 23, 2020

[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]

Re: Private Letter Ruling Request  
Account ID: [REDACTED]  
FEIN: [REDACTED]

Dear [REDACTED]:

The Department has completed its review of your request for a written determination on behalf of [REDACTED] ("Taxpayer"). In making this written determination, the Department has considered the facts presented in your initial request as well as any supplemental information provided to the Department for consideration.

This private letter ruling is a written determination issued under N.C. Gen. Stat. § 105-264.2 and applies the tax law to a specific set of existing facts furnished by you on behalf of Taxpayer. This written determination is applicable only to the taxpayer addressed herein and as such has no precedential value except to the taxpayer to whom the determination is issued.

### **Overview and Relevant Facts**

You state Taxpayer "is a manufacturer and distributor of medical devices used during minimally invasive surgical procedures. [Taxpayer's] products are disposable and one time use. Some of [Taxpayer's] products are used in therapeutic procedures and subsequently discarded; others are implanted in or attached to the human body to assist in the functions of blood circulation, digestion, excretion, and urination; other products are implanted in the human body to repair damage caused by injury or disease. The Taxpayer's products are primarily sold to physicians, hospitals, and other health care facilities, but sales are not restricted to licensed health care practitioners. Food & Drug Administration warning labels are included on all the [Taxpayer's] products. [Taxpayer] does not require a written prescription on purchases. Warning labels are required on [Taxpayer's] products indicating 'Caution: Federal law restricts this product to sale by or on the order of a physician.'

"[Taxpayer] currently invoices its customers for the price of the products in question below plus the applicable sales tax. However, [Taxpayer's] customers are claiming that these products are exempt from sales tax, because they fall under the North Carolina definition of prosthetic device exemption.

### **"Product #1- Ligators**

The [REDACTED] (hereinafter 'Ligator') is used to treat variceal bleeding, allowing multiple ligations to be performed with a single insertion of an endoscope. A ligator prevents blood loss by [tying]

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tissues during surgical procedures. The Ligator is packaged and sold with multiple bands that are implanted, a handle unit, trip wire, and irrigation catheter. All the related components are used once and discarded.

### **“Product #2- Anti-Bleeding Clips**

The [REDACTED] (hereinafter ‘anti-bleeding clips’) are used to stop bleeding or hemorrhage of blood through a vessel or organ of the body during surgery. The anti-bleeding clips are implanted and [are] packaged with a handle and detachable catheter, to be used during the procedure and then discarded.

### **“Product #3-Hemostasis Catheters**

The [REDACTED] and [REDACTED] [REDACTED] are used to stop gastrointestinal bleeding and designed to provide uniform burn and effective coagulation. The injection [REDACTED] probe is packaged with a hemostasis/irrigation catheter to be used during the procedure and then discarded.”

...

“Taxpayer sells and invoices these products as one unit/price and [does] not separately [sell] the delivery components nor have pricing for individual components in their book[s] and records. Products #1-3 are FDA approved as one product/unit. The related delivery components of the above items are critical and essential to the placement of the devices into the patients. . . the delivery devices (handle unit and irrigation catheter) are. . . inextricably connected to the use and deployment function for products #1-3 as a replacement, corrective, or supporting device worn on or in the body to prevent or correct physical deformity or malfunction and to support a weak or deformed portion of the body . . .”

In your email you responded to the Department’s questions and advised that with the Ligators and Anti-bleeding Clips “the bands and clips remain implanted” and with the Hemostasis Clips [REDACTED] [REDACTED] that the “product helps coagulate blood.” You stated that “[a]ll products are used to stop various kinds of bleedings or hemorrhages.”

### **Issue**

Are Taxpayer’s products, as described above, classified as prosthetic devices and, therefore, specifically exempted from North Carolina sales and use tax pursuant to N.C. Gen. Stat. § 105-164.13(12)a?

### **Applicable Statutes and References**

Under Article 5 (“Article”) of the North Carolina Revenue Act (“Act”)<sup>1</sup>, N.C. Gen. Stat. § 105-164.1 *et. seq.*, Subchapter VIII: Local Government Sales and Use Tax, and Chapter 1096 of the 1967 Session Laws, State, applicable local, and applicable transit rates of sales and use taxes are imposed on a retailer’s net taxable sales or gross receipts, as applicable, of tangible personal property, certain digital property, and certain services at the percentage rates listed in N.C. Gen. Stat. § 105-164.4(a). N.C. Gen. Stat. §§ 105-164.3(15), 105-164.3(123), 105-164.3(195), 105-164.3(223), 105-164.4, 105-467, 105-468, 105-483, 105-498, 105-507.2, 105-509.1, and 105-537.

N.C. Gen. Stat. § 105-164.3(159) defines the term “prosthetic device” as “[a] replacement, corrective, or supporting device worn on or in the body that meets one of the conditions [listed below]. The term includes repair and replacement parts for the device. The conditions are as follows:

- a. Artificially replaces a missing portion of the body.
- b. Prevents or corrects a physical deformity or malfunction.
- c. Supports a weak or deformed portion of the body.”

<sup>1</sup> References to the Act and North Carolina General Statutes are based on the laws in effect as of the date of issuance of this private letter ruling except as otherwise noted herein.

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N.C. Gen. Stat. § 105-164.13(12)a. provides, in part, an exemption from sales and use tax for the sale at retail and the use, storage, or consumption in this State of “[p]rosthetic devices for human use.”

The Streamlined Sales and Use Tax Agreement (“SSUTA”), Health Care Item List – Appendix L<sup>2</sup>, provides, in part, that “Staples, Sutures and Suture Alternatives” are used “to hold skin, internal organs, blood vessels and all other tissues of the human body together, after they have been severed by injury or surgery” and should be classified as a “Prosthetic device.”

### **Ruling**

Based on the information furnished, Taxpayer’s products (Ligators, Anti-bleeding Clips, and Hemostasis Catheters) are used to stop bleeding or hemorrhaging during surgical procedures. The Ligators and Anti-Bleeding Clips perform functions that are the same as or similar to staples, sutures, and suture alternatives since they are used to stop bleeding or hemorrhaging by tying and holding tissues, blood vessels, and skin together during surgery and meet the definition of the term “prosthetic device” as provided in N.C. Gen. Stat. § 105-164.3(159) by providing support to a weak or deformed portion of the body and by preventing or correcting a physical malfunction by stopping bleeding and preventing hemorrhaging during surgery. Pursuant to the provisions of N.C. Gen. Stat. § 105-164.3(159), Taxpayer’s sales of Ligators and Anti-Bleeding Clips are sales of prosthetic devices. Therefore, the Taxpayer’s sales of Ligators and Anti-Bleeding Clips are exempt from North Carolina sales and use tax under the provisions of N.C. Gen. Stat. § 105-164.13(12)a.

Based on the information furnished, the Hemostasis Catheters [REDACTED] are used to stop gastrointestinal bleeding and are designed to provide uniform burn and effective coagulation, the product is packaged with a hemostasis/irrigation catheter to be used during the procedure and then discarded. Since the product is connected to external equipment, then inserted into the body during surgery, used during the procedure, and discarded when the surgery is completed, the product is not worn in or on the body as provided in the definition of the term “prosthetic device” in N.C. Gen. Stat. § 105-164.3(159). Therefore, the Hemostasis Catheters do not meet the definition of the term “prosthetic device” as provided in N.C. Gen. Stat. § 105-164.3(159) and the sales of these products are not exempt from North Carolina sales and use tax under the provisions of N.C. Gen. Stat. § 105-164.13(12)a.

This ruling is based solely on the facts submitted to the Department of Revenue for consideration of the transactions described. If the facts and circumstances given are not accurate, or if they change, then the taxpayer requesting this ruling may not rely on it. If a taxpayer relies on this ruling and the Department discovers, upon examination, that the fact situation of the taxpayer is different in any material aspect from the facts and circumstances given in this ruling, then the ruling will not afford the taxpayer any protection. It should be noted that this document is not to be cited as precedent and that a change in statute, a regulation, or case law could void this ruling.

Issued on behalf of the Secretary of Revenue  
By the Sales and Use Tax Division

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<sup>2</sup> North Carolina is a member state of the SSUTA, a multistate effort to simplify and modernize sales and use tax administration. The Health Care Item List is available on the Streamlined Sales Tax website at: <https://www.streamlinedsalestax.org/>.