

MAHARASHTRA AUTHORITY FOR ADVANCE RULING

GST Bhavan, 1st floor, B-Wing, Mazgaon, Mumbai - 400010.

(Constituted under section 96 of the Maharashtra Goods and Services Tax Act, 2017)

BEFORE THE BENCH OF

(1) Shri B. Timothy, Addl. Commissioner of Central Tax, (Member)

(2) Shri B. V. Borhade, Joint Commissioner of State Tax, (Member)

GSTIN Number, if any/ User-id	27AADCN1920C1zZ
Legal Name of Applicant	Nipro India Corporation Private Limited
Registered Address/Address provided while obtaining user id	Plot No. E-1, MIDC Kesurdi, Taluka - Khandala, Dist. Satara -412 802
Details of application	GST-ARA, Application No. 141 Dated 28.03.2019
Concerned officer	Superintendent, Central Tax - Range I, Shirwal, Dist. - Satara
Nature of activity(s) (proposed / present) in respect of which advance ruling sought	
A Category	Factory/Manufacturing
B Description (in brief)	Nipro India Corporation Private Limited is engaged in the manufacture of various medical apparatus like Dialyzer, Cannula, Syringe, Blood Tubing Sets, Artificial Venous Fistula Needles, Diapers, etc.
Issue/s on which advance ruling required	(i) classification of goods and/or services or both
Question(s) on which advance ruling is required	As reproduced in para 01 of the Proceedings below.

PROCEEDINGS

(under section 98 of the Central Goods and Services Tax Act, 2017 and the Maharashtra Goods and Services Tax Act, 2017)

The present application has been filed under Section 97 of the Central Goods and Services Tax Act, 2017 and the Maharashtra Goods and Services Tax Act, 2017 [hereinafter referred to as "the CGST Act and MGST Act" respectively] by M/s **Nipro India Corporation Private Limited** , seeking an advance ruling in respect of the following questions.

- Q1. "Whether on facts and circumstances of the case, the product "Dialyzer" be treated as 'Disposable sterilized dialyzer or micro barrier of artificial kidney'as mentioned under Entry No. 255 of Schedule I to Notification Number 1/2017-Central Tax (Rate), dated 28 June 2017 and Notification Number 1/2017-Integrated Tax (Rate), dated 28 June 2017 (collectively referred to as the 'Rate Notifications')
- Q2. If the said product "Dialyzer" falls under Entry No. 255 of Schedule I to the Rate Notifications, whether it would be classified under Chapter 90 (i.e. Tariff item 9018 90 31) or Chapter 84 (i.e. Tariff item 8421 29 00).

At the outset, we would like to make it clear that the provisions of both the CGST Act and the MGST Act are the same except for certain provisions. Therefore, unless a mention is specifically made to any dissimilar provisions, a reference to the CGST Act would also mean a reference to the same provision under the MGST Act. Further to the earlier, henceforth for the purposes of this Advance Ruling, the expression 'GST Act' would mean CGST Act and MGST Act.

02. FACTS AND CONTENTION – AS PER THE APPLICANT

The submissions, as reproduced verbatim, could be seen thus –

Statement of the relevant facts having a bearing on the question raised

The relevant facts of the case are as follows:

Background of operations:

- 2.1. Applicant, a Pvt. Ltd company incorporated under the provisions of the Companies Act, 1956 holding GST regn no. ('GSTIN') 27AADCN1920C1ZZ with effect from 01.07.2017, is located at Plot No. E-1, MIDC, Kesurdi, Taluka-Khandala, Dist. Satara 412 801.
- 2.2. The Applicant is engaged in the manufacturing of medical equipments such as dialyzers, blood tubing sets, arterial fistulas, syringes and needles.
- 2.3. The Applicant runs a manufacturing facility at Shirwal, Maharashtra. Goods manufactured by the Applicant are sold within India and also exported outside India.

Product information:

- 2.4 Under the current application for advance ruling, the Applicant seeks to determine the classification of the product "Dialyzer".
- 2.5 The product 'Dialyzer' is a medical equipment/apparatus used for purification of blood. It is a life saving device, used in the Dialysis Machine for the dialysis treatment which separates blood impurities like urea/creatinine, etc. from the blood by the principle of diffusion through semi permeable membrane.

Questions before the Authority of Advance Ruling:

- 2.6 The Applicant has approached the Authority of Advance Ruling to determine the correct HSN classification of the product "Dialyzer".
- 2.7 Applicant believes that the product "Dialyzer" qualifies as 'Disposal sterilized dialyzer or micro barrier of artificial kidney' under Entry No. 255 of Sch. I to the Rate Notfn.
- 2.8 If the said product "Dialyzer" falls under Entry No. 255 of Schedule I to the Rate Notifications, whether it would be classified under **Chapter 90** (i.e. Tariff item 9018 90 31) or **Chapter 84** (i.e. Tariff item 8421 29 00).
- 2.9 The Applicant craves leave to submit such further facts at or before the hearing of the application as may be relevant.

Classification of Goods / Tariff Heading:

Product Name	Tariff Heading under Central Excise	HSN code Under GST	Basic Excise Duty Rate	GST Rate	Benefit of Notification of Central Excise
Hollow Fiber Dialyzers	9018 90 31 8421 29 00	9018 90 31 8421 29 00	-NIL-	5.00%	12/2016-CE dt. 01.03.2016
A V Fistula	9018 32 90	9018 32 90	6.00%	12.00%	12/2012-CE dt. 17.03.2012
Blood Tubing Sets	9018 90 32	9018 90 32	6.00%	12.00%	12/2012-CE dt. 17.03.2012
Disposable Syringes With Needles	9018 31 00	9018 31 00	6.00%	12.00%	12/2012-CE dt. 17.03.2012
Disposable Syringes Without Needles	9018 31 00	9018 31 00	6.00%	12.00%	12/2012-CE dt. 17.03.2012
Cannula	9018 39 30	9018 39 30	6.00%	12.00%	12/2012-CE dt. 17.03.2012
IV Catheter	9018 39 30	9018 39 30	6.00%	12.00%	12/2012-CE dt. 17.03.2012
Needles	9018 32 30	9018 32 30	6.00%	12.00%	12/2012-CE dt. 17.03.2012
Clinical / Adult Diaper	9619 00 40	9619 00 40	6.00%	12.00%	2/2011-CE dt. 01.03.2011
Rubber Stoppers	4016 99 80	4016 99 80	12.50%	18.00%	NA
Rubber Product-Other	4016 99 90	4016 99 90	12.50%	18.00%	NA

Statement containing the Applicant's interpretation of classification in respect of the aforementioned products

Applicant prefers to present the application before this Hon'ble Authority on the following, among other grounds, each of which is taken in the alternative & without prejudice to the others.

2.10. Applicant's interpretation of law or facts:

- (i) As mentioned above, current application for advance ruling is being made to determine if the product "Dialyzer" can be classified as 'Disposable sterilized dialyzer or micro barrier of artificial kidney under Entry No. 255 of Schedule I to the Rate Notifications.
- (ii) Relevant extract of Entry No. 255 of Sch. I to the Rate Notfn. has been reproduced for reference below:

S.No.	Chapter/ Heading/Sub-heading/ Tariffitem	Description of Goods
255	90 or 84	Disposable sterilized dialyzer or micro barrier of artificial kidney

- (iii) The terms 'Dialyzer' or 'Artificial kidney' have not been defined under the Rate Notfns. However, in terms of Explanation (v) to the Rate Notfns, the rules for the interpretation of the First Schedule to the Customs Tariff Act, 1975, including the Section & Chapter

Notes & the General Explanatory Notes of the First Schedule should, so far as may be, apply to the interpretation of the respective Rate Notfn.

- (iv) The competing entries in the present case for classification of the product "Dialyzer" are Heading 9018 and Heading 8421. The Applicants feel it proper to reproduce the text of Heading 9018 and 8421, for ease of reference:

9018 *Instruments and appliances used in medical, surgical, dental or veterinary sciences, including scientific apparatus, other electromedical apparatus and sight-testing*

9018 90 *Other instruments and appliances:*

9018 90 31 *Renal dialysis equipment (artificial kidneys, kidney machines and dialyzers)*

8421 *Centrifuges, including centrifugal dryers, filtering or purifying machinery and apparatus, for liquids or gases*

- *Filtering or purifying machinery and apparatus for liquids:*

8421 29 00 *Other*

- (v) On perusal of the afore-mentioned Headings (9018 and 8421), it is clear that Heading 9018 covers inter-alia "instruments and appliances for medical, surgical use" and Tariff Item 9018 90 31 specifically covers "**Renal dialysis equipment**", which includes "**artificial kidneys**" and "dialyzers", whereas Heading 8421 covers "filtering or purifying machinery and apparatus, for liquids and gases" and Tariff Item 8421 29 00 covers "Other filtering or purifying machinery and apparatus for liquid"

- (vi) **Meaning assigned under independent treatise:**

- (a) As per the trade parlance, artificial kidney is often a synonym for hemodialysis, but may also, more generally, refer to renal replacement therapies (with exclusion of renal transplantation) that are in use and/or in development.

- (b) As per Dr. Thiagarajan Thandavan, Ph.D. (Dialysis) M.Sc. (Renal Science and Dialysis) Certified lead auditor QMS, OHSAS and NABH Assessor of National Clinical Manager Dialysis -

This write-up is based on scientific reference articles published in journals.

Hemodialysis refers to the dialysis of blood, during which the patient's blood is passed through an artificial kidney or dialyzer (haemodialyzer) containing a membrane (2). The dialyzer, is a semipermeable membrane inside a polypropylene cylinder (3). Dialyzer is used in hemodialysis to filter out wastes and fluid from the bold of patient with kidney failure. Blood flows on one side of the membrane, whilst the other side is bathed by the electrolyte or salt solution (Dialysis fluid) continually produced by a proportionate system (Hemodialysis machine), which also monitors and controls treatment. Molecules

small enough to pass through the membrane, such as salts and low molecular protein breakdown products, tend to move in the direction of decreasing concentration. Larger substances, such as proteins and cells having dimensions greater than the pore diameter are retained. Hemodialysis is generally performed three times weekly for patients with irreversible renal or kidney failure, whilst the treatment regimens for acute or reversible renal failure are governed by clinical requirements and may include intermittent or continuous treatment over a period of several days.

References:

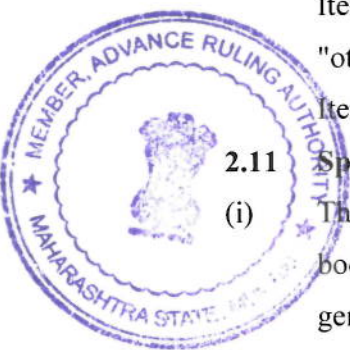
- *Kloff WJ, Berk HT, Jeter Welle M, et al. The artificial kidney, a dialyzer with great area. Acta Med Scand 1944; 117:121-128.*
- *Nicholas Hoenich. Cellulose for medical applications: Past, present and future. Bio Resources. 2006;1(2):270-280*
- *Core Curriculum of the Dialysis Technician, A comprehensive Review of Hemodialysis: fourth Edition: 2008:42,109,298*

- (vii) From the aforesaid extract, it is clear that "dialyzers" are used for the purpose of dialysis, i.e. purification of blood. The dialyzers are not used for filtration or purification of any liquids or gases. Therefore, the product in question should be classifiable under Tariff Item 9018 90 31, by its specific name "dialyzers", and not under a generic category of "other filtering or purification equipment or apparatus for liquids", falling under Tariff Item 8421 29 00.

2.11 Specific Heading preferred to Generic Heading for classification:

- (i) The product 'Dialyzer' is exclusively used for dialysis, i.e. purification of blood in human body, which is specifically covered under Tariff Item 9018 90 31, as compared to a general term "other filtering or purifying machinery and apparatus for liquids", falling under Tariff Item 8421 29 00.
- (ii) It is a well settled position of law that in case of any dispute on classification of a product, specific Heading has to be preferred to a generic Heading, in support which reliance is placed on the following judgments:
- i. Champdany Industries – 2009 (241) ELT 481 (SC)
 - ii. Speedway Rubber - 2002 (143) ELT 8 (SC)
 - iii. Plasmac Machine Mfg. – 1991 (51) ELT 161 (SC)
 - iv. VAC Met Corporation - 1985 (22) ELT 330 (SC)

2.12 Essential character/use of product relevant for classification:



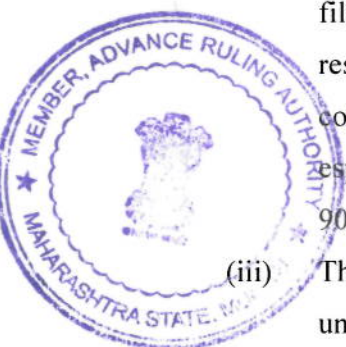
- (i) The Applicant submits that the essential use of “Dialyzers” is for dialysis, i.e. purification of blood in human body and not for filtration or purification of any other liquids or gases.
- (ii) It is a settled position of law that essential character/use of the products has also to be considered for classification; in support which reliance is placed on the following judgments:
 - i. Sprint R.P.G. India - 2000 (116) ELT 6 (SC)
 - ii. Fedders Llyod Corporation - 2001 (135) ELT 1331 (T)
 - iii. Prag Industries - 1998 (103) ELT 62 (T)

2.13 Principles of ejusdem generis and/or noistur a sociis:

- (i) Heading 8421 covers "filtering or purifying machinery and apparatus for liquids" which inter alia include ion exchanger plant or apparatus; household type filters; machinery and apparatus for filtering or purifying beverages, other than water; oil or petrol-filters for internal combustion engines.
- (ii) Applicants submit that even invoking the principles of ejusdem generis and/or noistur a sociis, the “Dialyzer” cannot be classified under Tariff Item 8421 29 00 as "other filtering or purifying machinery and apparatus”, as the same does not have any resemblance to the products covered therein, as blood in human body cannot be compared with any of the liquids meant filtration mentioned under the said Heading, especially in a case where “Dialyzer”, by name, is specifically covered under Tariff Item 9018 90 31.
- (iii) The “Dialyzer” would be classifiable under Tariff Item itself, as the products covered under Sub heading 9018 90 are medical or surgical instruments and appliances, having specific function, and hence, the product would correctly and appropriately fall in the family of those products under Sub-heading 9018 90 and to be precise under Tariff Item 9018 90 31. Further, the goods falling under Sub-heading 9018 90 are used for purification or transfusion of blood in human body, and hence, consigning the product to a generic group of "other filtration and purification equipment and apparatus for liquids" under Tariff Item 8421 29 00 would be incorrect.

2.14 Notes to Section XVI and Chapter 90:

- (i) As per Note 1(m) of Section XVI, under which Chapters 84 and 85 are covered, articles of Chapter 90 are not covered under the said Section XVI, which means goods covered under Chapter 90 cannot be classified under Chapter 84.
- (ii) Similarly, as per Note 2 to Chapter 90, “parts and accessories” for machines, apparatus, instruments or articles of Chapter 90 are to be classified according to the following rules:



- a. Parts and accessories which are goods included in any of the heading of Chapter 90 or of Chapter 84, 85 or 91 (other than heading 8487, 8548 or 9033) are in all cases to be classified in their respective headings;
 - b. Other parts and accessories, if suitable for solely or principally with a particular kind of machine, instrument or apparatus, or with number or machines, instruments or apparatus of the same heading (including a machine, instrument or apparatus of heading 9010, 9013 or 9031) are to be classified with the machines, instruments or apparatus of that kind
- (iii) Even if it is assumed that the Dialyzer is not an independent or separate equipment or apparatus and it cannot function on its own, but it is a part or accessory of Dialysis Machines and it works in combination with other equipment or apparatus, still the same would be correctly and appropriately classifiable under Tariff Item 9018 90 31, as based on Note 2 to Chapter 90, parts and accessories which are suitable for sole or principal use with a particular kind of machine, instrument or apparatus, or with number of machines, instruments or apparatus of the same Heading are to be classified with the machines, instruments or apparatus of that kind. Since, Dialyzer is meant for sole and principal use with Dialysis Machine, the same would be correctly and principally classifiable under the Heading meant for Dialysis Machine, i.e. Tariff Item 9018 90 31.

15. General Rules for Interpretation of tariff

(i) The Applicant submits that even invoking General Rules for Interpretation (GIR), the product "Dialyzer" would find appropriate parentage under Heading 9018 and not under Heading 8421, which would get substantiated from the following:

(ii) As per Rule 1 of GIR, firstly, the classification of a product has to be done by invoking the description in the Heading and corresponding Notes to Sections and Chapters, which if invoked, the product "Dialyzer" would be classifiable under Heading 9018, as Tariff Item 9018 90 31 gives the specific description of the product, i.e. Dialyzer or Artificial kidney and as per Note 1(m) to Section XVI, under which Chapters 84 and 85 are covered, articles of Chapter 90 are not covered under the said Section, which means goods covered under Chapter 90 cannot be classified under Chapter 84.

(iii) Further, if Rule 3(a) of GIR is invoked, the Heading which provides the more specific description has to be preferred to a Heading providing general description. In the present case, Tariff Item 9018 90 31 specifically describes the products thereunder as artificial kidneys, kidney machines and dialyzers.

(iv) Likewise, by invoking Rule 3(b) of GIR, the Heading which provides the essential character of the product has to be preferred for classification. In the present case,



Dialysis, i.e. purification of blood in human body, is the essential character of the Dialyzer and hence, the same would be classifiable under Heading 9018.

- (v) Similarly, even if the Rule 3c) of GIR is invoked, the Heading occurring last in numerical order has to be preferred. In the present case, when competing Headings 8421 and 9018 are compared, it is Heading 9018, which is occurring last in numerical order and hence, the said Heading has to be preferred, in comparison with Heading 8421, for classification of the product "Dialyzer"

2.16 Common parlance test:

- (i) Applicants submit that it is a common experience that the identity of an article is associated with its primary function inasmuch as a customer buys it to perform a specific function from it. In the present case, customers buy the Dialyzers for dialysis purposes and not for filtration or purification of any liquid. Therefore, the product in question is correctly classifiable under Tariff Item 9018 90 31, in support of which reliance is placed on the following judgments:

- i. Real Optical Co. - 2001 (129) ELT 7 (SC)
- ii. Fusebase Eltoto Ltd. – 1994 (67) ELT 30 (SC)
- iii. Atul Glass Industries – 1986 (25) ELT 473 (SC)

- (ii) Applicants further submit that the product in question is commercially known by the manufacturers, importers, dealers, user, etc. as "Dialyzer" meant for medical use for dialysis purposes, i.e. purification of blood in human body, and not meant for filtration or purification of any other liquids. Therefore, invoking commercial parlance test also, the product in question would be classifiable under Tariff Item 9018 90 31, in support of which reliance is place on the following judgments:

- i. Kedia Agglomerated Marbles – 2003 (152) ELT 22 (SC)
- ii. G.S. Auto International – 2003 (152) ELT 3 (SC)
- iii. Purewal Associates - 1996 (87) ELT 321 (SC)
- iv. Krishna Carbon Paper - 1988 (37) ELT 480 (SC)

2.17 Heading beneficial to the assessee:

- (i) Without prejudice to the above submissions, the Applicants submit that if the product in question equally merits classification under two different Headings, the classification one beneficial to the assessee has to be preferred, in support of which we place reliance on the Hon'ble Supreme Court judgment in the case of CCE v/s Minwool Rock Fibres Ltd., reported in 2012 (278) ELT 581 (SC), wherein it has been held as under:

Classification of goods - Two competitive headings of Excise/Customs Tariff - Heading beneficial to assessee to be adopted. [para 13]

2.18 Conclusion:

Basis the above submissions, the Applicant is of the view that the product "Dialyzer" merits classification under Tariff item 9018 90 31 and consequently as "Disposable sterilized dialyzer or micro barrier of artificial kidney' under Entry No. 255 of Schedule I to the Rate Notifications.

Further to above submissions, we most respectfully pray that:

- Allow us to reiterate all the submissions without prejudice to one another;
- Grant a personal hearing to put forth our contentions and explain our submissions before passing any order in this regard;
- Allow us to amend, alter and add to the present application;
- Allow us to produce additional documents and other material during the time of Personal Hearing and
- Pass such orders and directions as may be deemed proper and necessary.

2.19 Additional submissions

(i) We, Nipro India Corporation Private Limited ("Nipro India' or 'the Company'), holding GSTIN 27AADCN1920C1zZ, situated at Plot No. E-1, MIDC, Kesurdi, Khandala, Taluka-Khandala, Dist. Satara 412801, have filed an application for advance ruling before your good office for determining the classification of dialyzers under GST law. In this regard, we have attended the preliminary hearing held on 3 May, 2019.

(ii) The issue involved in the Application filed by the Company is relating to classification of the product "Dialyzers" manufactured by the Applicant. The question for consideration in the Application, is whether Dialyzers manufactured by the Applicant should be classified under HSN 9018 9031 or HSN 8421 2900. The Applicant presently classifies the products under HSN 8421 2900 on account of directions received by the Applicant from its jurisdictional officers under the erstwhile regime based on Customs Circular No. 19/2013 dated 9 May, 2013 (enclosed as **Exhibit A**). However, the Applicant is of the view that the product Dialyzers merits classification under HSN 9018 9031. We are hereby submitting a detailed write up of the oral submissions made during the course of the preliminary hearing held on 3 May, 2019, along with certain supporting material.

2.20 Judicial precedents:

(i) The Applicant wishes to place reliance on certain judgements pronounced under the erstwhile regime. The Applicant submits that in other identical cases under the erstwhile regime, higher authorities have pronounced judgments which have upheld the Applicant's contentions. It merits appreciation that the issue involved is prima facie covered in the following cases wherein Customs Circular No. 19/2013 dated 9 May, 2013 has been set aside by the respective High Courts in the following cases:

- Sanwar Agarwal v. Commissioner of Customs (Port) and Ors [2016 (336) ELT 42 (HC-Kol) - Enclosed as **Exhibit B**; and
- Additional Commissioner of Customs, Cochin v. Terumo Penpol Ltd [2017 (350) E.L.T. 74 (Ker.)]
- Enclosed as Exhibit C - Maintained by Hon'ble Supreme Court in Additional Commissioner v. Terumo Penpol Ltd. [2018 (360) E.L.T. A178 (S.C.)] – Enclosed as **Exhibit D**.

(ii) The above decision of the Kerala High Court in the case of Terumo Penpol Ltd. vs. Additional Commissioner of Customs, Cochin [2017 (350) E.L.T. 74 (Ker.)], was challenged before the Honorable Supreme Court in Special Leave Petition vide Diary No.2023/2017, and the said petition was dismissed. Whereas the Kolkata High Court judgement in the case of Sanwar Agarwal vs. Commissioner of Customers (Port) and Ors [2016 (336) ELT 42 (HC-Kol)], is pending before the Division bench of Calcutta High Court.

3.3 In view of this, the decision of Hon'ble Supreme Court has attained finality and is binding on the lower authorities as per Article 141 of the Constitution of India. Since issue in the present case is fairly covered by the judgement of Hon'ble Supreme Court, even though under the erstwhile regime, the Applicant is of the view that the product “Dialyzer” merits classification under Tariff item 9018 90 31 and consequently as 'Disposable sterilized dialyzer or micro barrier of artificial kidney' under Entry No. 255 of Schedule I to Notification Number 1/2017-Central Tax (Rate) dated 28 June, 2017 and Notification Number 1/2017-Integrated Tax (Rate) dated 28 June, 2017 (collectively referred to as the 'Rate Notifications’).

2.21 Meaning of the term “Disposable” used in “*Disposable sterilized dialyzer or micro barrier of artificial kidney*” under Entry No. 255 of Schedule I to the Rate Notifications

(i) During the course of the preliminary hearing, your good office expressed your intention to further delve into the meaning of the term “Disposable” used in “Disposable sterilized dialyzer or micro barrier of artificial kidney” under Entry No. 255 of Schedule I to the Rate Notifications, as ascertaining disposability of the product Dialyzer manufactured by the Applicant, would go a long way in determining whether it merits classification under Entry No. 255 of Schedule I to the Rate Notifications.

(ii) We would like to submit that since the term “Disposable” has not been defined in the GST law, we wish to place reliance on the dictionary meaning of the said term.

- The Cambridge dictionary defines "disposable" as "*intended to be thrown away after use*"
- The Oxford dictionary defines “disposable” in relation to an article as "*intended to be thrown away after use*"
- The Merriam-Webster dictionary defines “disposable” as "*designed to be used once or only a limited number of times and then thrown away*"

(iii) Further, based on the information available in the public domain [Source: Wikipedia], "A disposable product is a product designed for a single use after which it is recycled or is disposed as solid waste".

(iv) Additionally, your good office would appreciate that Dialyzer being a medical device used in blood purification and removing impurities, it cannot be used more than once i.e. the Dialyzer would have to be safely disposed of after single use, in order to avoid contamination.

(v) The Company, being a manufacturer of medical devices which are marketed globally, is required to display the information essential for proper use on the medical device, its packaging or in the associated documentation, in terms of ISO 15223-1 – "Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied". ISO 15223-1 identifies requirements for symbols used in medical device labelling that convey information on the safe and effective use of medical devices. It also lists symbols that satisfy the requirements of this part of ISO 15223. This part of ISO 15223 is applicable to symbols used in a broad spectrum of medical devices, which are marketed globally and therefore need to meet different regulatory requirements. We have enclosed the same herewith as Exhibit E.

(vi) The symbol required to be displayed on single use or disposable medical devices is given in Point 5.4.2 of Table 1 - *Symbols to convey information essential for proper use*. This

symbol indicates a medical device that is intended for one use, or for use on a single patient during a single procedure. Further, sterilized medical devices are also required to display a certain symbol given in Point 5.2.4 of Table 1, which indicates that the medical device has been sterilized using irradiation. We have enclosed images of the packaging of the product Dialyzer manufactured by the Company, on which such symbols are being displayed, as **Exhibit F**.

(vii) Further, we have also enclosed the Instructions for Use ('IFU') which are provided along with the Dialyzers, as **Exhibit G**. Under Point 3- "*Caution after use*", it has been clearly mentioned that the Dialyzers are for single use only and they should be disposed of immediately after use, by any means suitable for avoiding contamination.

(viii) Therefore, based on the above submissions, it is clear that the product Dialyzer manufactured by the Applicant is disposable in nature and the same has also been appropriately disclosed on the packaging of the product in terms of ISO 15223-1. Consequently, the product Dialyzer, merits classification under "Disposable sterilized dialyzer or micro barrier of artificial kidney" under Entry No. 255 of Schedule I to the Rate Notifications.

2.22 Additional documents:

(i) During the course of the preliminary hearing, your good office requested us to produce sample copies of invoices issued by the Applicant for supply of Dialyzers. We have enclosed the same as **Exhibit H**.

(ii) Further, the Applicant had provided a Letter of Authority along with the application for advance ruling, authorizing our representatives to appear before your good office. However, your good office has informed us that a power of attorney on INR 500 stamp paper would be required to be submitted, authorizing our representatives to appear before your good office. We have enclosed the same as **Exhibit I**.

(iii) Additionally, as mentioned during the course of the preliminary hearing and in the covering letter forming part of the application for advance ruling, the question raised in the application is not pending in any proceedings under the GST law. However, the same is pending under the erstwhile regime in the Applicant's case in multiple proceedings under the Central Excise Act, 1944 and Customs Act, 1962. In the notice for preliminary hearing issued by your good office, we have been requested to provide copies of show cause notices/ adjudication orders in respect of Central Excise or Service Tax issued during last five years. We have enclosed the same herewith as **Exhibit J**, for your reference.

(iv) Request you to acknowledge the receipt of this letter. Should you require any further information or clarification, we will be glad to provide the same.

03. **CONTENTION - AS PER THE CONCERNED OFFICER**

The jurisdictional office has not made any submissions.

04. **HEARING**

The case was taken up for Preliminary hearing on dt. 03.05.2019 with respect to admission or rejection of present application when Sh. Nitin Vijaivergia and Sh. Shivraj Mhaske, Advocates appeared and made oral submissions requesting for admission of their application. Jurisdictional Officer was not present.

The application was admitted and final hearing was held on 02.08.2019, Sh. Shivraj Mhaske, Advocates and Sh. Vipin Bang , Advocate appeared and made oral and written submissions . Jurisdictional Officer was not present.

05. **OBSERVATIONS**

We have gone through the facts of the case, documents on record and submissions made by both, the applicant as well as the jurisdictional office.

The subject matter concerns classification of the product, namely "Dialyzer" manufactured by the applicant. They have queried as to whether it would be classified under Chapter 90 (i.e. Tariff item 9018 90 31) or Chapter 84 (i.e. Tariff item 8421 29 00).

The applicant has submitted that the product 'Dialyzer' is a disposable, medical equipment/apparatus used in the Dialysis Machine for purification of blood during the course of

dialysis treatment which separates blood impurities like urea/creatinine, etc. from the blood by the principle of diffusion through semi permeable membrane. From a perusal of the submissions made by the applicant, we find that the subject product, classification of which is sought, is exclusively used in Dialysis Machines.

In medical parlance, dialysis is considered to be the process of removing excess water, solutes, and toxins from the blood in people whose kidneys can no longer perform these functions naturally. A Dialysis machine is a machine used in dialysis that filters a patient's blood to remove excess water and waste products when the kidneys are damaged, dysfunctional, or missing. The dialysis machine consists of plastic tubing that carries the removed blood to the 'dialyser' which is a bundle of hollow fibers that forms a semipermeable membrane for filtering out impurities. In the dialyser, blood is diffused with a saline solution called dialysate, and the dialysate is in turn diffused with blood. When the filtration process is complete, the cleansed blood is returned to the patient. Dialyzers are not used for filtration or purification of any liquids or gases.

We find that Chapter Heading 9018 covers Instruments and appliances used in medical, surgical, dental or veterinary sciences, including scientographic apparatus, other electromedical apparatus and sight-testing. Renal dialysis equipment (artificial kidneys, kidney machines and dialyzers) are classified under CSH 9018 90 31. From the submissions made by the applicant we find that the subject product does not make up a Renal Dialysis Equipment but it can very definitely be considered as a part of a renal Dialysis Equipment.

As per Note 2 to Chapter 90, "parts and accessories" for machines, apparatus, instruments or articles of Chapter 90 are to be classified according to the following rules:

- a. Parts and accessories which are goods included in any of the heading of Chapter 90 or of Chapter 84, 85 or 91 (other than heading 8487, 8548 or 9033) are in all cases to be classified in their respective headings;
- b. Other parts and accessories, if suitable for solely or principally with a particular kind of machine, instrument or apparatus, or with number or machines, instruments or apparatus of the same heading (including a machine, instrument or apparatus of heading 9010, 9013 or 9031) are to be classified with the machines, instruments or apparatus of that kind.

The Applicant has drawn our attention to the fact that the ambiguity in the classification of the product has arisen because of the Board's Circular No.19/2013 dated 09/05/2013 wherein it has been clarified that "Disposable Sterilized Dialyzer and Micro barrier for filtering blood" are correctly classifiable under 84212900. It was also informed that the JNCH Customs has not accepted an order-in-original of the Commissioner classifying the product in Heading 9018 and appealed against it in the CESTAT on the ground that though the Kerala High Court in the case

of *Terumo Penpol Ltd. vs. Additional Commissioner of Customs, Cochin* [2017 (350) E.L.T. 74 (Ker.)] upheld the classification of the product in the heading 9018 and the Supreme Court dismissed the department's appeal against it, it was dismissed in limine and hence cannot be considered as having attained finality. We have examined the question of classification of the impugned product in the context of this existing ambiguity and came to a finding that there is a conflict between the Board's Circular No.19/2013 dated 09/05/2013 and the Customs Tariff Act, 1975. Whereas the Board's Circular clarifies that the product should be classified in 8421 29 00, the First Schedule to the Customs Tariff Act, 1975 lists the item in the Heading 9018 as under:

9018 90 31 Renal dialysis equipment (artificial kidneys, kidney machines and dialyzers)

In this situation, we refer to a settled law that wherever there is a conflict between a *Rule/Regulation/Circular* and *an Act of Parliament*, the latter will prevail. In consideration of this finding alone, we come to the conclusion that the product in question is correctly classifiable under the tariff item 9018 90 31, since we have no doubt that the subject product is the same product specified in the eight digit code 9018 90 31 of the First Schedule to the Customs Tariff Act, 1975.

The applicant has queried whether "Dialyzer" can be classified as 'Disposable sterilized dialyzer or micro barrier of artificial kidney' under Entry No. 255 of **Schedule I** to the Rate Notifications. Entry No. 255 of Schedule I to the Rate Notifications is reproduced as under:-

S.No.	Chapter/ Heading/Sub-heading/ Tariffitem	Description of Goods
255	90 or 84	Disposable sterilized dialyzer or micro barrier of artificial kidney

Since a dialyzer is used in performing the functions of a kidney, it goes without saying that it is required to be sterilized and free from contamination. We are also of the opinion that given the importance of the subject product in performing the work of a kidney albeit externally, the same should not be reused. The table above mentions that the sterilized dialyzer should be disposable i.e for a single use purpose only. The applicant has contended that the subject product are disposable in nature and are marketed as such. We are in agreement with the contention of the applicant that the subject product is performing a very crucial function in the case of persons suffering from kidney failure and therefore very critical and with contamination can also lead to serious consequences in such patients. In normal circumstances and in all situations such dialyzers should not be reused and in fact are not being reused which therefore implies that they are disposed of after a single use.

In view of the above discussions and applicant's submissions, we hold that the subject product, namely, 'dialyzers' are used in sterilized form and are also disposable after single use. Hence the same will be covered under Entry No. 255 of Schedule I to the Rate Notifications.

06. In view of the deliberations as held hereinabove, we pass the order as under :

ORDER

(under section 98 of the Central Goods and Services Tax Act, 2017 and the Maharashtra Goods and Services Tax Act, 2017)

NO.GST-ARA- 141/2018-19/B- 94 Mumbai, dt. 23/08/2019

For reasons as discussed in the body of the order, the question is answered thus –

Question 1. "Whether on facts and circumstances of the case, the product "Dialyzer" be treated as 'Disposable sterilized dialyzer or micro barrier of artificial kidney' as mentioned under Entry No. 255 of **Schedule I** to Notification Number 1/2017-Central Tax (Rate), dated 28 June 2017 and Notification Number 1/2017-Integrated Tax (Rate), dated 28 June 2017 (collectively referred to as the 'Rate Notifications')

Answer :- **Answered in the affirmative.**

Question 2. If the said product "Dialyzer" falls under Entry No. 255 of Schedule I to the Rate Notifications, whether it would be classified under Chapter 90 (i.e. Tariff item 9018 90 31) or Chapter 84 (i.e. Tariff item 8421 29 00).

Answer :- **The product is classifiable in the tariff item 9018 90 31.**



—sd—
B. TIMOTHY
(MEMBER)

—sd—
B. V. BORHADE
(MEMBER)

Copy to:-

1. The applicants
2. The concerned Central / State officer
3. The Commissioner of State Tax, Maharashtra State, Mumbai
4. The Chief Commissioner of Central Tax, Churchgate, Mumbai
5. Joint commissioner of State Tax, Mahavikas for Website.

CERTIFIED TRUE COPY


MEMBER
ADVANCE RULING AUTHORITY
MAHARASHTRA STATE, MUMBAI

Note :- An Appeal against this advance ruling order shall be made before The Maharashtra Appellate Authority for Advance Ruling for Goods and Services Tax, 15th floor, Air India building, Nariman Point, Mumbai – 400021.