33TACD2021

BETWEEN/

[NAME REDACTED] LIMITED

Appellant

V

REVENUE COMMISSIONERS

Respondent

DETERMINATION

Introduction

1. This is an appeal against a Binding Tariff Classification (BTI) issued by the Respondent in relation to a product manufactured by the Appellant company namely, **[product name redacted]** an antimicrobial Basin Liner System *(hereafter the 'Basin Liner System').* The Appeal concerns the interpretation of headings 9018, 3922 and 3004 of the Combined Nomenclature set out in Annex I to Council Regulation (EEC) No 2658 of 23 July 1987, on the tariff and statistical nomenclature and on the Common Customs Tariff, as amended.

2. On 20 July, 2017, a BTI was issued by the Respondent classifying the product under CN heading 3922 (baths, shower-baths, sinks, washbasins, bidets, lavatory pans, seats and covers, flushing cisterns and similar sanitary ware, of plastics). This classification was based on the *basin liner system* comprising a set of three items with the basin, the material or component which gave the product its essential character. Classification under CN heading 3922 carries a rate of import duty of 6.5 per cent.

3. The Appellant company submitted that the product should be classified under CN heading 9018 which pertains to '*instruments and appliances used in medical, surgical, dental or veterinary sciences, including scintigraphic apparatus, other electromedical apparatus and sight-testing instruments*.' In the alternative, the Appellant submitted that the product could be classified under CN heading 3004 which pertains to *'Medicaments, consisting of mixed or unmixed products for therapeutic or prophylactic uses, put up in measured doses … or in forms or packings for retail sale*.' Classification under these CN headings carries a rate of import duly of zero per cent.

4. The Appellant issued a first stage formal appeal to the Customs Appeal Unit of the Respondent on 26 September, 2017. On 26 October, 2017, the Respondent's designated appeals officer issued his determination upholding the BTI classification under CN heading 3922 10 00. The Appellant duly appealed.

Background

5. The Appellant company manufactures the antimicrobial *Basin Liner System*. The product is an antimicrobial patient bathing system designed for use in a clinical setting to reduce the spread of healthcare acquired infections (HAIs). The Appellant's BTI application described the product as: *'a specially designed basin liner system consisting of a basin, a roll of single use disposable liner and a liner dispenser. The system is impregnated with embedded passive antimicrobial agents and is used to prevent the spread of pathogens and cross-contamination during patient bathing in hospitals.'*

6. Mr. **[name redacted],** a representative of the Appellant company stated that he started to research the product in 2010, after a close family member entered a facility for a period of respite and returned from the facility with a healthcare-acquired infection ('HAI'). In the years that followed he researched and developed the product. He stated that he developed the product specifically to be used to wash patients in a healthcare setting, in a manner that mitigated the risk of acquiring HAIs. The *Basin Liner System* has obtained CE approval in accordance with Directive 93/42.

7. The product consists of an external polypropylene container into which a disposable polyethylene liner is placed prior to filling with water for washing. The liners are

packaged in rolls and mounted on a dispenser. Both the outer container and the inner liner contain an antimicrobial agent (silver ion biocide) that kills microbes on contact. The product inhibits the spread of HAIs as the antimicrobial agent binds to and damages the cell wall of pathogens preventing growth and replication of these microorganisms. The properties of the silver ion biocide facilitate self-cleansing of the plastic and inhibit growth of micro-organisms by up to 99.99%.

8. The cover letter which accompanied the BTI application provided as follows: '[**Appellant company redacted**] *products are designed to treat and prevent the spread of hospital acquired infections in the healthcare environment. … The* [basin liner system] *is an antimicrobial basin liner system. The system provides high levels of pathogen technology to prevent the spread of pathogens during patient bathing and reduce the risk of cross-infections. …. This device is a plastic washbasin which has been impregnated with a silver ion biocide. The basin has been specifically designed to facilitate the attachment of the liners. ….The roll of single use disposable antiomicrobial liners is designed to be used in conjunction with the reusable basin. The liners are made of a low-density polyethylene that, like the basin, have been impregnated with Biomaster silver-ion biocide. This biocide is renowned for its capability in inhibiting the growth of many harmful bacteria and has been shown to have a kill rate of 99.99% against pathogens such as MRSA, E.Coli, VRE and Staphylococcus Aureus. This is especially critical in managing the spread of such bacterial in hospitals, clinics, etc. for patients.*'

9. The Appellant stated that the *Basin Liner System* provided lasting anti-microbial protection for the lifetime of the product as the silver ion biocide is integrated into the plastic and does not wear off over time. As skin cells that are shed during bathing do not come in contact with the basin itself, the risk of cross contamination between patients is eliminated. A new clean disposable liner for each patient is used to ensure complete cleanliness. The Appellant submitted that the use of an easy clean method of bathing patients is beneficial to hospital staff and patients as part of infection control policy. The result is that the product reduces the risk to patients in hospitals and care centres, of healthcare acquired infections (HAIs). On this basis the Appellant submitted that it was incorrect to classify the *Basin Liner System* as a standard plastic basin and that it should be classed as a medical device. The Respondent accepted that the *Basin Liner System*, when in use, had the potential to reduce the risk to patients in hospitals and care centres from acquiring HAIs. The Respondent's position was that

this particular function was not of itself sufficient to deem the product classification to be one within CN heading 9018 9084.

10. The Respondent, by letter dated 26 October, 2017, upheld the BTI classification under CN heading 3922 10 00. The Appellant duly appealed.

Legislation and legal context

11. The Customs Cooperation Council, now the World Customs Organisation (WCO), was established by the convention creating that council, concluded in Brussels on 15 December 1950. The Harmonised Commodity Description and Coding System ('the HS') was drawn up by the WCO and established by the International Convention on the Harmonised Commodity Description and Coding System ('the HS Convention') concluded in Brussels on 14 June 1983 and approved, with its amending protocol of 24 June 1986, on behalf of the European Economic Community by Council Decision 87/369/EEC of 7 April 1987.

12. Under Article 3(1) of the HS Convention, each Contracting Party undertakes to ensure that its customs tariff and statistical nomenclatures are in conformity with the HS, to use all of the headings and subheadings of the HS without addition or modification, together with their related numerical codes, and to follow the numerical sequence of that system. Each Contracting Party also undertakes to apply the General Rules for the interpretation of the HS and all the section, chapter and subheading notes of the HS, and not to modify their scope.

13. Council Regulation (EEC) No. 2658/87 of 23 July 1987 on the tariff and statistical nomenclature and on the common customs Tariff (hereafter 'the 1987 regulation') and Commission implementing Regulation EU 2016/1821 of 6 October 2017 amending Annex I to Council Regulation (EEC) No 2568/87 (hereafter 'the 2017 regulation') represent EU legislation directly applicable in Member States.

14. The combined nomenclature of the common customs tariff ('CN') is set out and established in Annex I to the 1987 regulation as amended. Customs classification of goods imported into the European Union is governed by the CN. The general rules for the interpretation of the CN, which are set out in Part One, Section I, of the CN, state

that classification of goods in the Combined Nomenclature shall be governed by six principles.

15. Those principles are as follows;

1. The titles of sections, chapters and sub-chapters are provided for ease of reference only; for legal purposes, classification shall be determined according to the terms of the headings and any relative section or chapter notes and, provided such headings or notes do not otherwise require, according to the following provisions.

2. (a) Any reference in a heading to an article shall be taken to include a reference to that article incomplete or unfinished, provided that, as presented, the incomplete or unfinished article has the essential character of the complete or finished article. It shall also be taken to include a reference to that article complete or finished (or falling to be classified as complete or finished by virtue of this rule), presented unassembled or disassembled.
(b) Any reference in a heading to a material or substance shall be taken to include a reference to mixtures or combinations of that material or substance with other materials or substances. Any reference to goods of a given material or substance shall be taken to include a reference to goods consisting wholly or partly of such material or substance. The classification of goods consisting of more than one material or substance shall be according to the principles of rule 3.

3. When, by application of rule 2(b) or for any other reason, goods are prima facie classifiable under two or more headings, classification shall be effected as follows:

(a) the heading which provides the most specific description shall be preferred to headings providing a more general description. However, when two or more headings each refer to part only of the materials or substances contained in mixed or composite goods or to part only of the items in a set put up for retail sale, those headings are to be regarded as equally specific in relation to those goods, even if one of them gives a more complete or precise description of the goods;

(b) mixtures, composite goods consisting of different materials or made up of different components, and goods put up in sets for retail sale, which cannot be classified by reference to 3(a), shall be classified as if they consisted of the

material or component which gives them their essential character, in so far as this criterion is applicable;

(c) when goods cannot be classified by reference to 3(a) or (b), they shall be classified under the heading which occurs last in numerical order among those which equally merit consideration.

4. Goods which cannot be classified in accordance with the above rules shall be classified under the heading appropriate to the goods to which they are most akin.

5. In addition to the foregoing provisions, the following rules shall apply in respect of the goods referred to therein:

(a) camera cases, musical instrument cases, gun cases, drawing-instrument cases, necklace cases and similar containers, specially shaped or fitted to contain a specific article or set of articles, suitable for long-term use and presented with the articles for which they are intended, shall be classified with such articles when of a kind normally sold therewith. This rule does not, however, apply to containers which give the whole its essential character;

(b) subject to the provisions of rule 5(a), packing materials and packing containers presented with the goods therein shall be classified with the goods if they are of a kind normally used for packing such goods. However, this provision is not binding when such packing materials or packing containers are clearly suitable for repetitive use.

6. For legal purposes, the classification of goods in the subheadings of a heading shall be determined according to the terms of those subheadings and any related subheading notes and, *mutatis mutandis,* to the above rules, on the understanding that only subheadings at the same level are comparable. For the purposes of this rule, the relative section and chapter notes also apply, unless the context requires otherwise.

16. The nomenclature is governed by the HS Convention, which was elaborated under the auspices of the World Customs Organisation ('WCO'). In the EU the HS Nomenclature was given the force of law in the 1987 Regulation.

17. As an aid to the correct classification of goods, the WCO has produced explanatory notes ('HSENs').

18. The CNs and HSENs under consideration in this appeal are as follows;

19. CN heading 9018 relates to: *'Instruments and appliances used in medical, surgical, dental or veterinary sciences, including scintigraphic apparatus, other electro-medical apparatus and sight-testing instruments*'

20. The HSEN relating to CN 9018 provides: '*This heading covers a very wide range of instruments and appliances which, in the vast majority of cases, are used only in professional practice (e.g. by doctors, surgeons, dentists, veterinary surgeons, midwives), either to make a diagnosis, to prevent or treat an illness or to operate, etc. Instruments and appliances for anatomical or autoptic work, dissection, etc., are also included, as are, under certain conditions, instruments and appliances for dental laboratories (see Part (II) below). The instruments of the heading may be made of any material (including precious metals).'*

The heading does not cover:

…

Sanitary ware of base metal (in particular headings 73.24, 74.18 and 76.15)

…..

….

It should also be noted that a number of the instruments used in medicine or surgery (human or veterinary) are, in effect, tools (e.g. hammers, mallets, saws, chisels, gouges, forceps, pliers, spatula, etc.) or articles of cutlery (scissors, knives, shears, etc.). Such articles are classified in this heading only when they are clearly identifiable as being for medical or surgical use by reason of their special shape, the ease with which they are dismantled for sterilisation, their better quality manufacture, the nature of the constituent metals or by their get-up (frequently packed in cases or boxes containing a

set of instruments for a particular treatment: childbirth, autopsies, gynaecology, eye or ear surgery, veterinary cases for parturition, etc.)

The instruments or appliances classified here may be equipped with optical devices: they may also make use of electricity, either as motive power or for transmission, or as a preventive, curative or diagnostic agent.'

21. CN heading 3004 relates to*: 'Medicaments (excluding goods of heading 3002, 2005 or 3006) consisting of mixed or unmixed products for therapeutic or prophylactic uses, put up in measured doses (including those in the form of transdermal administration systems) or in forms or packages for retail sale.'*

22. The HSEN relating to CN 3004 provides: *'This heading covers medicaments consisting of mixed or unmixed products, provided they are: Put up in measured doses or in forms such as tablets, ampoules (for example, re-distilled water, in ampoules of 1.25 to 10cm [cubed], for use either for the direct treatment of certain diseases, e.g., alcoholism, diabetic coma or as a solvent for the preparation of iniectible medicinal solutions) capsules, cachets, drops or pastilles, medicaments in the form of transdermal administration systems, or small quantities of powder, ready for taking as single doses for therapeutic or prophylactic use*.'

23. CN heading 3922 covers: *'Baths, shower-baths, sinks, wash-basins, bidets, lavatory pans, seats and covers, flushing cisterns and similar sanitary ware, of plastics*.'

24. The HSEN relating to CN 3922 provides: *'This heading covers fittings designed to be permanently fixed in place, in houses, etc., normally by connection to the water or sewage systems. It also covers other sanitary ware of similar dimensions and uses, such as portable bidets, baby baths and camping toilets. Flushing cisterns of plastics remain classified in his heading whether or not equipped with their mechanisms. However, the heading excludes: (a) Small portable sanitary articles such as bed pans and chamber-pots (heading 39.24).'*

Submissions *in brief*

25. The Appellant submitted that the appropriate CN classification for the *Basin Liner System* was within CN Heading 9018 on the basis that the product was an appliance

used in medical science which prevented illnesses and mitigated the spread of contagious illnesses, infections and diseases including but not limited to MRSA, E-Coli, staphylococcus aureus and Vancomycin-resistant enterococci ('VRE').

26. In the alternative, the Appellant submitted that the *Basin Liner System* came within CN Heading 3004 which pertains to *'Medicaments, consisting of mixed or unmixed products for therapeutic or prophylactic uses, put up in measured doses … or in forms or packings for retail sale*.

27. The Respondent submitted that its classification of the product within CN heading 3922 (baths, shower-baths, sinks, washbasins, bidets, lavatory pans, seats and covers, flushing cisterns and similar sanitary ware, of plastics) should stand. The Respondent's classification was based on the *Basin Liner System* comprising a set of three items with the basin, the material or component which gave the product its essential character.

Evidence

28. Oral evidence on behalf of the Appellant was provided by Professor. A, Associate Professor of Microbiology. Oral evidence on behalf of the Respondent was provided by Witness B, Chartered Engineer.

Evidence of **[Professor A]**

29. Evidence on behalf of the Appellant was provided in an expert capacity by Professor A, Associate Professor of Microbiology, **[redacted]** College Dublin.

30. The Professor stated that he had 40 years' experience working in microbiology and immunology, that he was **[redacted]** of the Irish Decontamination Institute and **[redacted]** of the advisory committee on decontamination to the HSE. He stated that he conducted a review of decontamination in Irish hospitals from **[redacted]** and that he had drawn up national guidelines for decontamination of medical instruments.

31. In 2014, the professor carried out a study to compare samples taken from used *Basin Liner System* devices with samples taken from standard basins, in order to compare their ability to inhibit growth or reduce challenge doses of a selection of bacteria applied to their surfaces for periods of 24 or 72 hours. Prior to the study, the devices had been in daily use at the **[redacted]** hospital, Dublin, for approximately five months, alongside regular untreated polypropylene basins.

32. The study concluded that after three days, high counts of bacteria were able to survive in viable form and were recoverable from standard polypropylene surfaces. However, the study concluded that the *Basin Liner System* devices showed a marked contrast to those recorded for polypropylene. The survival rates for all bacterial species tested were very significantly less than on polypropylene basins and this was regardless of whether the bacteria were in contact for 24 hours or 72 hours. There was no significant difference between the antimicrobial performance of the *Basin Liner System* device whether in new and unused state or after five months in use.

33. The study found that all *Basin Liner System* device samples were capable of reducing challenge bacterial counts by greater than 99% at 24 hours and by 99.99% at 72 hours. The professor prepared a report setting out his methodology and results. The study concluded that '*This antimicrobial performance for the* [Basin Liner System] *device shows definite potential for infection control in clinical usage*.'

34. In his oral evidence the professor stated that the use of various items in hospitals including other standard basins were capable of causing grievous harm to patients. He stated that HAIs were lethal in some cases.

35. He stated that he had tracked a number of MRSA infections which were caused by the use of non-antimicrobial basins. He stated that there was no doubt in his mind that the *Basin Liner System* was a medical device. He stated that its attributes were proven in many areas of biofilm control and in microbial control.

36. His evidence was that with repeated use, ordinary basins become scoffed on the surface, start to deteriorate and over time and become impossible to clean, sanitise or sterilise. He stated: '*They are even more lethal at that stage*.' He stated that the *Basin Liner System* had a tougher plastic, did not have the same cleaning requirements and '*shouldn't deteriorate in the same way'*.

37. He stated that all three items in the *Basin Liner System* (namely, the basin, the liners and the dispenser) '*are acting as something to break the chain of infection and protect the patient.'* He continued: *'So in busy wards and people carrying these things around from one person to another or from one area to another, it will stop the spread of infection which is the biggest problem in hospitals at the present time*.'

38. During cross-examination, the professor stated that the *Basin Liner System* was not specifically for care assistants who are washing patients but that it was for treating at-risk groups including people with wounds, with skin conditions and people who are susceptible. He stated that the product was to prevent infection and to deliver infection control.

39. During cross-examination, the professor agreed that silver ion biocide has been around for approximately 30 years and that it is used in a variety of products including table tops, trays, paint and chopping boards.

40. He stated also that the *Basin Liner System* would have had a better quality manufacture than an ordinary plastic basin.

Evidence of **[Witness B]**

41. Evidence on behalf of the Respondent was provided in an expert capacity by **[Witness B]** chartered engineer, fellow of the Institution of Engineers of Ireland and consultant engineer.

42. In his written report dated 5 December 2018, **[Witness B]** stated that the use of silver ion biocide is widespread throughout a range of industries and products including table tops, paints and flooring covers. He stated that the fact that a product uses the silver ion biocide does not mean it is a medical device.

43. **[Witness B]** confirmed that he had examined the basin and the dispenser. He confirmed that the differentiating feature of the *Basin Liner System* basin was its embedded antimicrobial agent, namely the silver ion biocide and that the silver ion biocide reduces the spread of infections.

44. He provided evidence in relation to the quality markings and their significance including the CE mark and Directive 93/42.

45. He stated that silver ion biocide is used to reduce the spread of infections in a multitude of products and environments such as table tops, floor paints, latex gloves, plastic storage containers, toothbrush holders, chopping boards and machinery parts.

46. He stated that the concept of putting a plastic liner in a basin was not unique, referencing a product in use in the United States, titled the 'basin glove liner' pictures of which are contained at Appendix 4 of his report. He also stated that he had found a number of manufacturers of microbial liners incorporating silver ion biocide which are used in various waste products that might contain microbes.

47. He stated that there were other antimicrobial liners available on the market and that these are not used uniquely in hospital or medical environments. He concluded his report by stating that: *'The use of the* [Basin Liner System] *product would not be limited exclusively to a medical or hospital environment. These could be used also for example in nursing homes, children's creches and laboratories.'*

48. [**Witness B]** stated that the *Basin Liner System* was generic in nature and not a precise medical device. He stated: '*... essentially it is a basin. It has got antimicrobial property but it is not used by medical specialists by way of intervention or cure*.'

49. There was no dispute from **[Witness B]** on the question of whether the *Basin Liner System* basin would be safer for patients. **[Witness B]** accepted the evidence of the professor and stated that the silver ion biocide would reduce pathogens and prevent cross-contamination and that such an attribute would be favourable for a hospital. He accepted that the silver ion biocide was a vital component in the mitigation of risk as opposed to a standard plastic basin or bag and that the *Basin Liner System* provided a higher standard of care for patients.

50. **[Witness B]** accepted that the *Basin Liner System* would be used on multiple occasions to wash multiple patients including immunity compromised and intubated patients.

51. In relation to the Appellant's submission that the product could fall within CN code 3004 which relates to 'medicaments' **[Witness B]** stated that medicaments referred to medicine. He stated: *'Clearly this is not a medicine'*.

Material Findings of Fact

52. Based on the evidence of Professor A, his report dated 26 November 2014, and noting also the fact that the evidence was accepted by the Respondent, I find, as a material fact that the *Basin Liner System* is a product which prevents illness and prevents the spread of infectious and/or contagious illness including but not limited to MRSA, E-Coli, staphylococcus aureus and Vancomycin-resistant enterococci ('VRE').

ANALYSIS

CN Heading 3004

53. As an alternative to CN Heading 9018, the Appellant contended for classification in accordance with CN heading 3004 which relates to*: 'Medicaments (excluding goods of heading 3002, 2005 or 3006) consisting of mixed or unmixed products for therapeutic or prophylactic uses, put up in measured doses (including those in the form of transdermal administration systems) or in forms or packages for retail sale.'*

54. I am satisfied that the *Basin Liner System* is not a medicament and I accept the evidence of the Respondent's witness in this regard when he stated that the Appellant's product was not a medicine.

CN Heading 3922 10 00

55. The general rules for the interpretation of the Combined Nomenclature which appear in Part One, Section 1, of the CN state that classification of goods in the combined nomenclature shall be governed by six principles. The Respondent relied on general interpretative rule 3(b), used for the classification of sets which provides: *'mixtures,*

composite goods consisting of different materials or made up of different components and goods put up in sets for retail sale, which cannot be classified by reference to 3(a), shall be classified as if they consisted of the material or component which gives them their essential character, in so far as this criterion is applicable.' The Respondent submitted that the product falls within CN Heading 3922 when one looks at the objective characteristics of the product in question.

56. The Respondent classified the *Basin Liner System* as an item of plastic sanitary ware under CN Heading 3922 10 00 on the basis that it comprised a set made up of a basin as the essential item and a dispenser as the ancillary item with the single use liners.

57. The Respondent also declined classification on the basis that HSEN 9018 provided a non-exhaustive list of the type of items that comprise instruments and appliances for human medicine or surgery and that neither the *Basin Liner System* nor any similar products were listed. The Respondent relied on the fact that the HSEN to 9018 specifically excludes sanitary ware of base metal, which includes washbasins. The Respondent stated that this interpretation extended to analogous products of plastic.

58. The Respondent referred to a number of tariff classification cases, cross rulings and Commission Regulations in its submissions, some of which considered the same CN Headings as those under consideration in this appeal. In Appeal Case C-152/10, *Unomedical A/S v Skaatteministeriet,* the Court of the Seventh Chamber ruled that dialysis drainage bags did not fall within CN Heading 9018 because the function of the drainage bag being the collection of urine, did not enable the catheter to perform its function, namely, the draining of the bladder. Accordingly, the bags were classified as articles of plastic under CN3926 90 99. In this appeal however, the Appellant submitted that in addition to utilisation in bathing patients, the washbasin itself prevents the acquisition of HAIs due to the antimicrobial qualities of the basin and on this basis the Appellant submitted that the product prevented illness as envisaged by CN 9018.

59. The most significant European Law tariff classification case for the purposes of this appeal, is ECJ Case C-547/13, *Oliver Medical SIA v VID.* The judgment of the Tenth Chamber, handed down on 4 March 2015, provides considerable guidance in relation to the matters under appeal herein. The case arose from a preliminary ruling concerning the interpretation of headings 8543, 9018 and 9019 of the CN. The

product which required classification, was a specialist device which used laser technology for the treatment of dermovascular and dermatological problems. The Court ruled that the apparatus was excluded from classification under heading 9018 because it did not provide any medical treatment and was not used in the practice of medicine. The relevant criteria are contained at paragraphs 47 – 59, as follows;

47Finally, for the purposes of classification under the appropriate heading, it should be recalled that the intended use of a product may constitute an objective criterion for classification if it is inherent to the product, and that inherent character must be capable of being assessed on the basis of the product's objective characteristics and properties (see judgment in Olicom, C-142/06, EU:C:2007:449, paragraph 18).

48With regard to heading 9018 of the CN, it is apparent from an examination of that heading that it covers, in particular, medical instruments or appliances. The wording of that heading does not give any more details on the characteristics of those instruments or appliances. Included in the list of goods covered by that heading is ultraviolet or infrared irradiation equipment.

49In that regard, it is necessary to note that, in accordance with the explanatory note to the HS concerning heading 9018, that heading covers a very wide range of instruments and appliances the normal use of which, in the vast majority of cases, requires the intervention of a practitioner, such as a doctor, surgeon, dentist, veterinary surgeon or midwife, to make a diagnosis, to prevent or treat an illness or to operate.

50It follows therefrom, firstly, that those appliances and instruments are, in most cases, used by a healthcare practitioner, without the intervention of such a practitioner being required in every case, and, secondly, that those appliances and instruments are intended for medical use.

51In order to establish whether a product is intended for medical use, it is appropriate to take account of all the relevant factors in the case, as set out in the order for reference, to the extent that they are characteristics and objective properties inherent to that product. It is for the importer, at the time of import, to prove that that product is intended for medical use.

52Among the relevant factors, it is necessary to assess the use for which the product is intended by the manufacturer and the methods and place of its use. Thus, the fact that the product is intended to treat one or more different pathologies and that that treatment must be carried out in a medical centre and under the supervision of a practitioner are indications capable of establishing that that product is intended for medical use. Inversely, the fact that a product

mainly brings about aesthetic improvement, that it may be operated outside a medical environment, for example in a beauty parlour, and without the intervention of a practitioner are indications that that product is not intended for medical use.

53The fact that a product bears a CE mark certifying the conformity of a medical device with the provisions of Directive 93/42 constitutes one factor among others to be taken into consideration in that regard. None the less, since Directive 93/42 pursues objectives different from those of the CN and in order to maintain the coherence between the interpretation of the CN and that of the HS, which is established by an international convention to which the European Union is a contracting party, the fact that a product bears a CE mark cannot be decisive as regards an assessment of whether it is intended for medical use within the meaning of heading 9018 of the CN.

54The referring court is also doubtful as to the relevance of other factors, such as the dimensions, the weight of the product under consideration and the technology used, in order to assess whether that product comes under heading 9018 of the CN. It takes the view that the goods at issue in the main proceedings must be distinguished on the basis of those factors from those which were covered by Regulation No 119/2008 and in respect of which the Commission excluded, in that regulation, classification under heading 9018 of the CN.

55It must be borne in mind in that regard that a classification regulation is of general application in so far as it does not apply to an individual trader but, in general, to products which are the same as that examined by the Customs Code Committee. In the interpretation of a classification regulation, in order to determine its scope, account must be taken, inter alia, of its statement of reasons (judgment in Krings, C-130/02, EU:C:2004:122, paragraph 33 and the case-law cited).

56It is true that Regulation No 119/2008 is not directly applicable to the goods at issue in the main proceedings. Those goods are not identical to those covered by that regulation, since they differ in size and weight, inter alia, as well as in the technology which they use.

57Nevertheless, the application by analogy of a classification regulation, such as Regulation No 119/2008, to products similar to those covered by that regulation facilitates a coherent interpretation of the CN and the equal treatment of traders (see, to that effect, judgment in Krings, EU:C:2004:122, paragraph 35).

58In accordance with the reasons given in the third column of the annex to Regulation No 119/2008, classification under heading 9018 of the CN as a medical instrument or appliance of the goods listed in the first column of that annex is excluded as the apparatus does not provide any medical treatment and is not used in the practice of medicine.

59It is appropriate to deduce therefrom that the dimensions, weight and technology used are not decisive factors for the classification of a product under that heading.

60. The relevant criteria are considered in the context of this appeal herein, as follows;

Directive 93/42

61. On the matter of Directive 93/42, I accept the submission of the Respondent that a CE mark is not conclusive on the matter of tariff classification however, the judgment of the Tenth Chamber in *Oliver Medical* (paragraph 53) confirms that a CE mark is a factor among others, to be taken into consideration and in this regard, I note that the Appellant's product obtained CE approval.

The use for which the product is intended by the manufacturer

62. Mr. **[name redacted],** a representative of the Appellant company, stated that he started to research the product in 2010, after a close family member entered a facility for a period of respite and returned from the facility with a healthcare acquired infection. In the years that followed he researched and developed the product that eventually became the *Basin Liner System*. He stated that he developed the product specifically for use in healthcare settings to mitigate the risk of HAIs including *MRSA, E.Coli, VRE and Staphylococcus Aureus.*

63. In its statement of case, the Appellant company submitted: *'... the* **unique [product name redacted]** *Basin Liner System ... is manufactured under Medical Device ISO: 13485. The antibacterial additive which is introduced during a specialised manufacturing process into the composition of the material inhibits the growth of bacteria – this has been independently tested and has a proven kill rate of 99.99% for many of the harmful species of bacteria which ultimately lead to health care acquired infections. The independent tests mentioned were carried out by* **[redacted]** *College Dublin, Ireland and* **[redacted]** *Services Ltd. United Kingdom to define their medical device status.'*

64. . The Respondent stated that Revenue did not make the case that the product did not have positive benefits or that it would not be beneficial in a hospital setting. The Respondent accepted that the *Basin Liner System* was more hygenic than a normal plastic basin but submitted that that did not change the fundamental objective characteristics or attributes of the basin. The evidence of the effectiveness of the *Basin Liner System* in preventing the spread of HAIs when compared with standard basins was accepted by the Respondent and the Respondent's expert witness.

Method of use, place of use and supervision by a medical practitioner

65. The Appellant submitted that a number of medical instruments (*i.e.* scissors, knives, shears) which have been classified as medical instruments under CN Heading 9018, could be used in a non-medical context by an individual. The Appellant submitted that the fact that the *Basin Liner System* could be used beyond the context of professional healthcare practice, was not a sufficient basis for its exclusion from CN heading 9018.

66. The Respondent's position was that such items are classified under CN Heading 9018 where in the vast majority of cases, they *'are used only in professional practice (e.g. by doctors, surgeons, dentists, veterinary surgeons, midwives), either to make a diagnosis, to prevent or treat an illness or to operate..'.*

67. The Respondent stated that a number of instruments used in medicine or surgery are, in effect, tools or articles of cutlery and that they are classified as coming under CN 9018 only where they are clearly identifiable as being for medical or surgical use by reason of their special shape, by the ease with which they are dismantled for sterilisation, by their better quality manufacture or by the nature of their constituent materials. The Respondent's position, as set out in correspondence dated 26 October 2017, was that the *Basin Liner System* was not deemed by the Respondent to meet these criteria.

68. The Appellant submitted that the *Basin Liner System* was to be differentiated from a standard washbasin by virtue of its better quality manufacture and in particular, the embedding through the plastic, of the antimicrobial silver ion biocide. The evidence of Professor A, in reference to manufacture of the product, was that the *Basin Liner System* would have had a better quality manufacture than an ordinary plastic basin.

69. While the *Basin Liner System* basin may not present as an item which is clearly identifiable as being for medical use, I consider that the better quality manufacture of the *Basin Liner System*, in particular the addition of the antimicrobial silver ion biocide, materially differentiates it from a standard washbasin, for tariff classification purposes.

70. On the matter of supervision, the Appellant submitted that the function of bathing and washing an individual who is confined to a bed is likely to take place predominantly in clinical settings such as hospitals, nursing homes, retirement homes and care homes.

71. The Respondent's position was that the *Basin Liner System* would require the supervision of a care assistant but not the supervision of a clinician.

72. The question of the level of supervision would, it seems, require that consideration be given to the condition of the patient who required bathing. The Appellant referred to patients who were burn victims, patients who were very seriously ill and those who were intubated. In such situations, care and skill in the bathing process would be paramount. If the patient had a contagious disease or virus, the bathing process would arguably require the supervision of a nurse or carer skilled in containment of the disease. It is conceivable that a very experienced nurse or perhaps a clinician would be required in a minority of instances, depending on the contagion involved.

73. As regards place of use, the Respondent accepted that the product could be put to use in nursing homes, retirement homes and care homes but accepted that the product could also be put to use in private homes. The Respondent submitted that this indicated that the product was not a medical appliance.

74. In the event that the product was put to use in the home (i.e. as a regular washbasin or in caring for a patient convalescing at home) this might support the Respondent's view that the appliance was not a medical appliance however, I do not consider that the weight to be attached to home use of this particular product is such as would result in the automatic classification of the product within CN heading 3922, albeit it is a factor to be taken into consideration.

Treatment of pathologies and prevention of illness

75. As stated above, the evidence of the effectiveness of the *Basin Liner System* in preventing the spread of HAIs, was not disputed in this appeal.

76. The Respondent's first stage appeal letter dated 26 October, 2017, upholding the Respondent's BTI classification under CN heading 3922 10 00, provided that: '*I acknowledge that due to the passive antimicrobial technology, the use of the … Basin Liner System has the potential to reduce the risk to patients in hospitals and care centres from acquiring healthcare acquired infections (HAIs). I further note the conclusion from the clinical studies the … Basin Liner System was subjected, However this is not in itself sufficient grounds to deem this product classification to be under CN heading 9018 9084.'*

77. The letter also provided that: *'… the .. Basin Liner System is not an instrument or appliance used to make a diagnosis, to prevent or treat an illness or to operate on a person and is therefore excluded from tariff heading 9018.'*

78. On the matter of the prevention of illnesses, the letter provided: *'Preventing an illness within the meaning of heading 9018 is achieved by medical intervention rather than by good hygiene practice.'*

79. The Appellant in its submission robustly contested the Respondent's submission that prevention of an illness within the meaning of heading 9018 is achieved only by medical intervention as opposed to by good hygiene practice. The Appellant's position was that this statement was manifestly incorrect. In his closing submission, Mr. **[name redacted]** on behalf of the Appellant, referred to the wellbeing of staff who work on the front line on a daily basis. He stated that the *Basin Liner System* mitigated the spread of hospital acquired infections and could have a bearing on whether someone lived or died. He stated that it was incomprehensible to him to consider that a patient, a baby or an elderly person might be washed with an unclean basin. He stated that people have given up their lives on becoming infected with HAIs.

80. The Respondent argued that cleanser units, disinfectant sprays and cleaning equipment did not come within CN Heading 9018 and that a washbasin similarly, should not be classified under CN Heading 9018. However, evidence led by the Appellant, which was not disputed by the Respondent, was that in care settings, standard washbasins become vehicles for the transmission of infection and disease. Based on the evidence of Professor A, including his report dated 26 November 2014, I have found as a material fact that the *Basin Liner System* prevents illness and prevents the spread of infection and disease including but not limited to MRSA, E-Coli, staphylococcus aureus and VRE. In all the circumstances, I determine that the appropriate tariff classification for the Appellant's antimicrobial *Basin Liner System* is a classification within Combined Nomenclature Heading 9018.

Determination

81. For the reasons set out above, I determine that the appropriate tariff classification for the Appellant's *Basin Liner System* is a classification within Combined Nomenclature Heading 9018.

82. I determine that the *Basin Liner System* does not fall within Combined Nomenclature Heading 3922, nor within Combined Nomenclature Heading 3004

83. This appeal is determined in accordance with s.949AL TCA 1997.

COMMISSIONER LORNA GALLAGHER

31st day of December 2020

The Tax Appeals Commission has not been requested to state and sign a case for the opinion of the High Court in respect of this determination.