

Procurement of Medical Devices for Clinical Centre Dr Dragiša Mišović

IOP/6-2017/RD

Clarification no. 13

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Question 1:

“2.1.1 Rotary Heat Sealers for bonding sterilization foil 1”

- a) In item 2 it is required that the device is made of stainless steel. These devices are always made of a combination of different materials, such as stainless steel, plasticized steel, plastic parts, aluminium, etc. The description doesn't specify which part of the device needs to be made of stainless steel.
Please allow offering of devices made of various materials, or specify that the housing of the device needs to be made of stainless steel, plasticized sheet metal, aluminium and similar, i.e. made of “stainless materials”.
- b) In item 3 it is required that the device should have an LCD screen. It is not specified whether this screen should be a touch screen. These touch screens drastically facilitate the work of operators, visibility of data, and similar.
In line with modern trends for this type of equipment, please make a correction in your requirement and state that the device needs to have a touch screen with a certain diagonal, for instance no smaller than 4”.
- c) In items 11 and 12 it was specified that the device can memorize 2.000 different texts and there is a possibility to rotate the text for 180°. These are very debatable requirements which may point to one manufacturer. In addition to that, there is no practical reason for such a requirement. Please remove the technical requirements from items 11 and 12.
- d) In item 14 it is required that the device has the RS232 connector for external connection to computers. Modern devices usually have the Ethernet or USB connection to external devices.
Please make a correction in this requirement and allow offering of devices that have the RS232 and/or Ethernet and/or USB connection to external devices such as PC.
- e) In item 19 it is required that the device should have the possibility to set the temperature for heat sealing in the range 50-199°C. Such a requirement doesn't make any sense in practice because bags are sealed at the temperature of 120° and higher.
Please make a correction in this requirement and allow offering of devices that have the option to set the temperature in the range 100-200°C
- f) In item 20 it is required that the maximum power of the device is 365 W. This is a very unusual requirement, because the value of 365 W itself has no real

significance, taking into account that the single phase socket that the device is connected to can provide significantly greater power.

Please remove the requirement for the maximum power.

- g) In item 21 the maximum dimensions of the device are given. Maximum dimensions significantly limit competition, and make no practical sense, since this device is usually placed on the working surface usually longer than one (1) metre. Please either remove this requirement defining the maximum dimensions of the device or define them as approximate dimensions with the prefix approx.

- h) In item 24 there are additional standards and directives listed that the device needs to adhere to. Since item 23 has already defined the most important standard prescribing this type of equipment, we see no need for listing the others, particularly if they refer to national standards of certain countries, as it is the case with the DIN standard here.

Please completely remove the requirement from item 24.

Answer 1:

- a) The Purchaser accepts the suggestion and states that the casing of rotary heat sealer should be made of stainless steel.
- b) The Purchaser accepts the suggestion and states that it is acceptable to offer the rotary heat sealer with LCD display or touch-screen monitor.
- c) The Purchaser considers this position to be fully justified, since it allows labeling the date and time of the packaging/sterilization, expiration date for sterility of the material, ward to which the material belongs and the like. In this way, productivity is raised during the manipulation of sets and contains all the relevant data related to the given set.
- d) The Purchaser accepts the suggestion and states that the rotary heat sealer should have USB and Ethernet connection for external devices.
- e) The Purchaser considers this position to be justified, as it enables sealing of the materials that will be used throughout the whole exploitation period of the sealer, and which demand temperatures below 100°C, such as PVC bags.
- f) The Purchaser maintains its request in order to reduce power consumption (energetic efficiency)
- g) The Purchaser maintains its request, as the larger device would reduce manipulative space at the working top of the table.
- h) The Purchaser maintains its request; the standards listed in item 24 are quality standards for this type of equipment.

Question 2.

“2.1.3 Roll holders with cutting device”

- a) In item 1 it is required that the device should be made of stainless steel. Sliders and the knife itself should logically be made of stainless steel as a durable and “sanitary” material, but there are parts of the device that are by their nature made of other materials.
- b) In item 2 it is required that the knife should be self-sharpening. The issue of a self-sharpening knife is very debatable because it leaves the possibility that micro “splinters” of stainless steel can appear and can end up in the sterilization bag before the packaging of the material.
- c) In item 5 the maximum dimensions of the device are given, which by themselves have no significance because the effective width (capacity) of the device is given in the previous item.
Please either completely remove this requirement with the maximum dimensions or define them as approximate dimensions with the prefix “approx.” in order to increase competition.

Answer 2:

- a) The Purchaser accepts the suggestion and stating that all elements of the roll holder should be made of stainless steel, except knife handle and roller on which rolls slide.
- b) The Purchaser considers this position to be justified because continuous "self-sharpening" friction of surfaces of similar solidity and minimal speeds of movement during cutting do not produce any micro metal particles. We would have completely different situation with the friction on grindstone or material of higher solidity (grinding).
- c) The Purchaser maintains its request as bigger dimensions of the device would restrict manipulative area.

Question 3:

“2.1.4 Trolley for transport of sterile material”

- a) In item 5 it is required that the trolley should have wheels with diameter min. 160 mm which “do not leave traces”, with several more insufficiently clear requirements. The 160 mm diameter is quite big and unusual for this type of equipment, which significantly reduces competition.
Please make a correction in the description, i.e. simplify it by saying, without specifying the minimum wheels diameter, that 4 wheels are required, with at least 2 of them with brakes, which is how they are usually made.
- b) In item 6 the maximum dimensions of the trolley are given in a very restrictive way, which is not needed taking into account the defined capacity of the trolley (6 STU).
Please define the size of the trolley in a less restrictive manner, for instance 1000 x 800 x 1600 mm.

Answer 3:

- a) The Purchaser considers that this position is justified because large wheels enable easier rolling over uneven surfaces, and as our hospital is pavilion-type hospital, we have to consider a lot of curbs and other uneven surfaces during manipulation.
- b) Purchaser considers that this position is justified because the dimensions given in the specification are determined in order to allow unhindered communication in all places in the hospital where the material is to be delivered.

Question 4:

“2.1.5 System for tracking and tracing in the system of sterile instruments supply”

- a) In item 12 it is required that “every place in the chain” should have the adequate hardware.
If possible, please explain in more detail where those places are located and how many of them there are, or if this is left to manufacturer’s choice.
- b) In items 10 and 11 it is defined that the system should also cover the delivery and the place of use of the instruments. It has been proven in practice that such a system is too complex and requires a significantly long implementation. From practical reasons it is much better to envisage a system covering the movement of instruments from their entry into central sterilization to their exit. It is also desirable to envisage possible future upgrades of this system.
Please make a correction in this part of the technical requirements, and completely remove the requirements from items 10 and 11.
- c) In item 16 it is not defined clearly enough that the system has the possibility to recognize the missing and insert new elements into the system. We assume that what is meant is that the system allows certain worn out instruments to be taken out of the system and new ones inserted into the database.
Please either remove this requirement or reword it by giving a clear explanation that the system is expected to be able to remove the existing and insert new elements.

Answer 4:

- a) The Purchaser accepts the suggestion and states that the system should be incorporated in the following points: reception, washing and disinfection, packing, sterilization, delivery and place of use of material.

- b) The Purchaser considers that this position is justified and clearly predicted that there is “the place of use of the material” in order to be able to determine the phase in which the material is in the moment of the search.
- c) The Purchaser considers that this position is justified because this characteristic allows the administrator to update sets’ information when there is a change in their content by adding, taking out, or combining.

Question 5:

“2.1.6 Chairs without back rest”

- a) Already in the name of the item it is determined that the chairs should not have a back rest. This is highly unusual, since the operator is sitting for long periods the working premises for sterilisation, the ergonomic approach where the chairs have a back rest is used in practice.
Please change this item by requiring that the chairs have a back rest (“Chairs WITH back rest”).
- b) Items 2, 3, 4 talk about the quality of the material the chairs are made of. The material of the chairs is irrelevant compared to the other important features such as the option to set the back rest and height, ergonomics and similar.
Please remove the requirements from items 2, 3, 4.
- c) In item 5 it is required that the chair should have foot adjustable height, for hands free at surgery. This is an illogical requirement because the chairs are not used at surgery but in the sterilization department.
Please make a correction in the description of this item and allow any usual ways of adjusting height, regardless of whether this is done by foot or hand.
- d) Item 6 defines the dimensions of the chair in an extremely narrow range. The external dimensions of such equipment are completely irrelevant, and the only value that makes any sense is the value for setting the height.
Please remove the technical requirement from item 6.

Answer 5:

- a) The Purchaser considers that this position is justified and clearly states that the use of backrest in central sterilization is unnecessary, in function and in design, and is completely different from the laboratory or office chair, and therefore did not provide a backrest for this position.
- b) The Purchaser considers that this position is justified because the material the chair is made of is very important for proper maintenance, for prevention of interaction with cleaning agents and disinfectants, all in order to prevent hospital infections.

- c) The Purchaser accepts the suggestion and states that the chair should have foot adjustable height in order to keep operator's hands free.
- d) The Purchaser considers that this position is justified because besides height adjustment range, the dimensions of the chair are also important and they are determined in accordance with the ergonomic requirements and operators' manipulation area.

Question 6:

"2.2 Automatic steam sterilizer"

- a) In item 1 you state that it is required that the sterilizer has one horizontal opening door with electromechanical locking. We would like to point out that horizontal opening doors for this type of sterilizers are a completely out-dated solution with a series of flaws, so in most cases in the practice the doors with vertical automatic or manual opening are used. This way you are not only requesting an out-dated technical solution, but also reducing competition without any reason. Please make a correction in your request, and allow offering of sterilizers with vertical sliding doors.
- b) In item 4 you state that the minimum allowed sterilizer volume is 70 litres. We would like to point out that item 3 has already defined the capacity of the sterilizer at 1 STU. Therefore, the minimum chamber volume is irrelevant, as long as the chamber has the required capacity expressed in STU. Please make a correction in this requirement in order to increase competition and allow offering of sterilizers with the minimum volume of 60 litres.
- c) In item 10 it is required that the sterilizer has a vacuum pump with water ring. The vacuum pump with water ring is typical for higher volume sterilizers, while with lower volumes – up to 100 litres, other solutions are also used, such as the injector (venturi) vacuum pump, which are in certain conditions even more efficient than the pump with water ring. Please make a correction in this requirement and allow offering of sterilizers that have a vacuum pump and the injector (ejector, venturi) type.
- d) In items 16 and 17 it is required that the sterilizer should have sterilization cycles for instruments at 134°C and textile at 134°C. On modern sterilizers with a higher degree of automation, one and the same programme is used for sterilization of different materials at 134°C. Please clarify, i.e. confirm that you will accept sterilizers with one sterilization cycle at 134°C which is used for different types of medical materials (textile and instruments).
- e) In item 23 you stated that the sterilizer should have a steam generator with "submerged" heaters with maximum power of 7.5 kW. The way this requirement is formulated eliminates the devices having a more advanced solution with heaters that are not in the direct contact with water. Such steam generator systems with heaters that are not submerged into water allow for incomparably longer lifetime of heaters compared to those that are submerged. This way you not only insist on a worse technical solution but eliminate all manufacturers who implement a more modern technical solution.

- i) In item 25 the maximum dimensions of the device are given. Since this is a freestanding device, the dimensions are not a critical parameter. In order to increase competition, please make a correction in the technical requirement and allow offering of devices with the maximum dimensions of 175 x 65 x 90 cm (height x width x depth), or define the maximum allowed dimensions as “approximate”, i.e. add the prefix “approx.”.

Answer 6:

- a) The Purchaser considers that this position is justified because this type of door opening of is recognized as an ideal solution for access to both the entire opening of the chamber and to the whole door seal during replacement. The possibility of injury caused by door crushing is minimized as the operator closes the door itself to the movements around the vertical axis and controls the closing pressure. Furthermore, the potential bidder has not confirmed or pointed to the shortcomings of this system by any single allegation, and we do not take this observation as a relevant.
- b) The Purchaser considers that this position is justified as during the exploitation of the sterilizer we do not use only containers of 1 STU volume or 1/2 STU, but very often we use packed material of dimensions exceeding the dimensions of the sterilization units. With this characteristic, we want the chamber to be fully utilized and to use the sterilizer of this kind to the maximum during exploitation.
- c) The Purchaser considers that this position is justified because the vacuum pump with a water ring is less affected by the sudden drops of pressure in the public water supply system and thus is much more reliable.
- d) The Purchaser considers that this position is justified because the cycle intended for sterilization of textiles implies a longer drying phase during the sterilization cycle, due to the difficult evacuation of moisture from the textile itself. In order to prevent unduly prolonging of the sterilization cycle where only instruments are sterilized, it is logical to have 2 sterilization cycles on 134°C, which basically has been standard for decades.
- e) The Purchaser considers that this position is justified because the devices that have heaters that are not submerged in water require longer heating period in order to achieve working temperature, which causes greater power consumption. Also, the devices must be constantly under voltage, even when the operator is not present, which is in conflict with valid legal acts.

Question 7:

“2.3 Air/space disinfection based on Ag/H₂O₂ solution“

- a) Both in the name of the device and in item 1 it is said that a device using colloidal silver (Ag) for stabilization of H₂O₂ is required. Colloidal silver is a hazardous substance that can accumulate in the body, which can cause serious and permanent health problems. Pharmaceutical medicine has practically rejected the colloidal silver not just because of the potential health problems it causes but also because its efficiency to destroy microorganisms is debatable. Moreover, according to the Rulebook dietary products of the Republic of Serbia from 2010, the colloidal silver products are not allowed to be on the shelves in pharmacies, i.e. should not be allowed to be used as a supplement to dietary products due to its potentially harmful effects. Finally, in the European Union it is not allowed to use colloidal silver not even as a biocide, which is the case in the public procurement in question.
- It is clear that the equipment beneficiary in the public procurement in question, probably unconsciously and without having the sufficient essential information, insists precisely on a device using a product which is practically banned – colloidal silver.
- In order to protect the employees in the health care institution of the beneficiary, please make a correction in this technical requirement, and contrary to the current requirement, do not allow offers of devices using colloidal silver.
- b) Item 4 requires that the product used by the device has neutral fragrance. This is a very broad definition, and in addition, such devices are in the largest number of cases used in premises where there are no people, so the existence of certain fragrances is irrelevant.
- Please remove this requirement as completely irrelevant.
- c) In item 5 it is defined that the maximum mass of the device is 6 kg. Nowhere has it been mentioned whether the device should be mobile on wheels, or be hand-held during the application of the biocidal product. In this regard, if the device is mobile on wheels or even if it is in the form of a freestanding device, the maximum mass can certainly be larger.
- Please redefine your requirement, and accept hand-held devices with mass up to 10 kg and freestanding or mobile devices on wheels whose mass doesn't matter.
- d) In items 6, 7, 8, 9 certain technical requirements for the device are defined which completely limit competition because they are very restrictive. On the other hand, one very important requirement is not defined, and that's the contact time, which guarantees the efficiency of the biocidal product.
- Please remove the technical requirements from items 6, 7, 8, 9 and add a new requirement which defines the contact time after which the products stops being efficient, 30 minutes maximum.
- e) In item 11 you define that the device should be produced in line with the quality systems ISO 9001 and ISO 13485. We'd like to highlight that ISO 13485 contains practically all elements from ISO 9001, so in this case it is not needed to require both quality systems. It is enough to have ISO 13485 which concerns the quality management system precisely in the production of products used in health care institutions.

Please make a correction in this requirement, and declare as acceptable the devices whose manufacturers use the quality system ISO 13485 in their operations, but not necessarily ISO 9001.

- f) In item 12 it is stated that the device can treat the volume of 1000 m³. This requirement is not defined precisely enough, because every device can treat an infinitely large volume as long as there is enough of the biocidal product. We assume that the Purchaser wanted to say that the device can treat a certain working volume with one charge of the biocidal product.

At the same time, for hand-held devices (devices carried in hands during application) 1000 m³ is quite a large volume, because most of these devices are used for premises of significantly smaller volume.

Please make a correction in this requirement, and allow offering of devices that can treat 800 m³ or more with one charge of the biocide.

Answer 7:

- a) The Purchaser maintains its request in which the air/space disinfection device based on Ag / H₂O₂ solution is required. The bactericidal activity of such concept is based on the production of OH⁻ radicals that can transfer electrons to the membrane of the bacteria and change its polarity. In this technologic solution, silver is used in very small dosage as catalyst and is completely safe.
- b) The Purchaser maintains its request. After the application of disinfectant and return to room, the bidder must guarantee a neutral smell without the need for ventilation.
- c) The Purchaser maintains its request. Given that in practice there is a need for frequent mobility, we consider this requirement essential. At the same time, the light weight of the device is necessary due to the manner of its use by adequate staff.
- d) The Purchaser maintains its request. All these requirements are in accordance with the needs of the Purchaser. The Purchaser requires that the device has a delayed start and to enable the staff to leave the room before the disinfection process begins. Venturi effect is required in order to get the effect of spraying (aerosols).
- e) This question has already been answered in the Clarification no. 5. It is allowed to submit ISO13485 instead of ISO9001.
- f) The request is completely defined in accordance with the Purchaser's needs and the volume required for the treatment, and we maintain the requested conditions.

Question 8:

"2.4.1 Automatic steam sterilizer"

- a) In item 1 it is stated that the sterilizer should have a sliding horizontal electro-mechanical door. This is a very unusual requirement which is not only unnecessarily restrictive, but also illogical, since for the past 20 years in 90% of the cases sterilizers with sliding vertical doors have been installed in health care

institutions in Serbia (in central sterilizations), which is a modern solution. Horizontal sliding electro-mechanical doors that the Purchaser insists on only have an unnecessary impact on significantly increasing the size of the device. Finally, the Purchaser requires an electro-mechanical door, and doesn't allow the far more practical and modern solution of the door operated by a pneumatic cylinder.

Please make a correction in this requirement, and require offering of the device with a sliding vertical door, operated by a pneumatic cylinder, because this by far the most practical and modern solution for sterilizers with capacity of 6 STU and 8 STU, as it is the case here.

- b) In item 4 it is required that the sterilizer has the loading height of max. 500 mm. This is an unusually low height, which doesn't completely correspond to the ergonomic requirements of central sterilizations. It is clear that this request is aligned with the requirements from item 1, which further achieves the restrictiveness of the specifications, although there is no special need for that. Please completely remove the requirement defining the maximum loading height.
- c) Item 7 defines the material of the sterilizer chamber as AISI 316L (CrNiMo stainless steel), and item 8 defines the material of the jacket as AISI 316 Ti (NiCrMo Ti stainless steel). It is unusual that it is required that these two components are made of different materials, since the jacket is welded to the chamber in its full circumference, while not being exposed to bigger loads compared to the chamber. AISI 316L represents a sort of a standard for this type of equipment, so insisting on another material is quite a restrictive requirement which unnecessarily limits competition.
- d) In item 11 it is said that the sterilizer should have an electromotor driven chamber door. This is a requirement leaning on the requirement from item 1. We repeat that this means insisting on a lower quality solution, and it is blocking offering of devices with more modern solutions, i.e. in this case the door moving vertically (up-down) by a pneumatic cylinder.
Please make a correction in this requirement, and require offering of the device with a sliding vertical door, operated by a pneumatic cylinder, because this by far the most practical and modern solution for sterilizers with capacity of 6 STU and 8 STU, as it is the case here.
- e) In item 16 it is said that the sterilizer should have heat insulated piping. We would like to highlight that heat insulation is only done for the pipes going through a hot fluid, i.e. water steam. Insulation of the other pipes makes no sense. By the way, this requirement is unnecessary, because it is taken for granted that a sterilizer meeting certain safety measures prescribed by the European standards will have insulated pipes which go through hot fluids and which the operator can come into contact with.
Please make a correction in this requirement, by completely removing the requirement for the heat insulated piping, or by highlighting that heat insulated piping is only needed for the pipes through which water steam goes.
- f) In item 18 you highlighted that the sterilizer should have a touch screen with the minimum diagonal of 10". However, it is not highlighted that the sterilizer should also have such a screen on both the sterile and non- sterile side.

Please specify the technical requirement by saying that it is necessary that the sterilizer has a touch screen with the minimum diagonal of 10" on both the sterile and non- sterile side.

- g) In items 22 and 23 it is said that the sterilizer should have the sterilization cycles for instruments at 134°C and textile at 134°C. On modern sterilizers with a higher degree of automation, one and the same programme is used for sterilization of different materials at 134°C.

Please clarify, i.e. confirm that you will accept sterilizers with one sterilization cycle at 134°C which is used for different types of medical materials (textile and instruments).

- h) In item 28 it is said that the sterilizer should have the electronic "Bowie&Dick" test. This requirement is completely unnecessary because in item 25 it has already been said that the sterilizer should have the "Bowie&Dick" test programme. We assume that this is a mistake by accident which can also be interpreted as a restrictive requirement.

- i) Item 39 gives the maximum allowed dimensions of the sterilizer at 1920x1600x1000mm (height x width x depth). Such dimensions can be interpreted as a very restrictive requirement, which has no practical significance. Namely, there is a height in the room which allows installing a device 2200 mm high. Width is as always critical, because installing wider devices prevents later capacity expansion by adding another device – there is not enough space in the room. Depth is definitely extremely restrictive, because it defines the sterilizer of the 9-6-6 type which is practically made by only one manufacturer.

Please make a correction in your technical requirement concerning the external dimensions of the sterilizer, and accept devices with a chamber that is usually used in health care institutions. In that regard, and with the aim of increasing competition, we suggest defining the external device dimensions as max. 220 x 120 (without the service space) x 140 cm (height x width x depth)

- j) Tender documents envisage procurement of 2 identical steam sterilizers. However, in the practical sense it is very desirable to envisage procurement of a combined steam-formaldehyde sterilizer instead of one of the steam sterilizers. This device has the ability to work as a regular steam sterilizer, with the option of sterilizing thermolabile materials at low temperatures using formaldehyde. The beneficiary obviously opted for in-house sterilization of thermolabile materials through procurement of a plasma sterilizer, which by its nature has a series of limitations concerning the type of materials which can be sterilized in it. By also procuring one combined steam-formaldehyde sterilizer the beneficiary gets the possibility to sterilize practically all thermolabile materials and in greater quantity, with keeping the necessary capacity of steam sterilization.

Please take our suggestion into consideration and subdivide the item 2.4.1 into two items: 1 x steam sterilizer, 1 x steam-formaldehyde sterilizer with the same specifications as the steam sterilizer, with the option for low temperature sterilization using liquid formaldehyde at the temperatures of 55–80°C.

Answer 8:

- a) The Purchaser considers that this position is justified because the concept of a sterilizer with horizontally-operated doors exists in the portfolios of all companies involved in the

production of steam sterilizers. Calling for more modern and reliable solutions without specifying any facts that support such observation can be categorized into the domain of speculation and as such we will no longer consider it. Electro-mechanical doors are certainly a better solution for the safety of the operator because apart from the mechanical interruption of power supply by activating the protective bar, it also has a coupling that slips on a certain force and thus prevents crushing.

- b) The Purchaser considers that this position is justified because it was defined in order to fulfill ergonomic requirements and enable easier manipulation of the material.
- c) The Purchaser considers that this position is justified because chamber and jacket are joined by welding, but the functions of the chamber and the duplicator are completely different, as well as the straining of the material during the cycle. Having this in mind, the optimal materials for these two parts of the steam sterilizer are prescribed.
- d) The Purchaser considers that this position is justified because the electro-mechanical doors are certainly a better solution for the safety of the operator because apart from the mechanical interruption of power supply by activating the protective bar, it also has a coupling that slips on a certain force and thus prevents crushing. Besides, the horizontal movement of the door completely eliminates the role of the gravity as a risk factor due to unforeseen circumstances.
- e) The Purchaser considers that this position is justified because besides the steam installations and condensation installations that are hot and whose insulation reduces heat emission and prevents burns during the device maintenance, the insulation of the cold water pipeline eliminates the formation of condensation on the pipes themselves and eventual dripping on parts of the sterilizer where it can cause damage or leave marks.
- f) The Purchaser accepts the suggestion and states that the sterilizer should have a touch screen of minimum 10 " diagonal on the non-sterile side of the device. On the sterile side of the device panel with door opening button and light signaling of the status of the sterilizer is sufficient.
- g) The Purchaser considers that this position is justified because the cycle intended for sterilization of textiles implies a longer drying phase during the sterilization cycle, due to the difficult evacuation of moisture from the textile itself. In order to prevent unduly prolonging of the sterilization cycle where only instruments are sterilized, it is logical to have 2 sterilization cycles on 134°C, which basically has been standard for decades.
- h) The Purchaser considers that this position is justified because the electronic Bowie & Dick test is an independent device that monitors steam penetration and evacuation of condensate during any selected cycle and signals malfunction in the functioning of the

sterilizer immediately after its creation without waiting for the Bowie & Dick test a special cycle in the period determined by the hospital protocol.

- i) The Purchaser considers that this position is justified because each steam sterilizer emits a certain amount of heat that, according to the laws of physics, moves from a lower to a point of maximum height. In order to enable adequate elimination of the heated air, and increase the volume of the heated air, and thus reduce its temperature in the area above the sterilizer, it is necessary to provide as much space for such operation. Furthermore, horizontal door sterilizers provide unhindered service access from the front side within their dimensions, so the marking of the width with or without service access is irrelevant. And finally, the depth of the device is very critical information because the Purchaser has limited space in both non-sterile and sterile area, and uninterrupted manipulation of the material must be maintained, which is achieved by reducing the depth and, with that, the length of the transport trolley.
- j) The Purchaser clearly outlined its needs in this public procurement and considers that the purchase of a steam-formaldehyde device is not necessary, and this issue will not be taken into consideration.

Question 9:

“2.4.2 Plasma sterilizer”

- a) Item 1 defines the sterilization temperature at 50–55°C. The sterilization temperature in one cycle can vary somewhat, so it is more convenient, in order to allow a larger number of bidders to participate in the public procurement procedure, to somewhat increase this range.
Please take our request into account and allow offering of a device with the working sterilization temperature in the range 50–60°C.
- b) Items 8-12 define the sterilization programmes, along with the length of the cycle, in a very vague manner, which can most likely be understood by only one manufacturer, which indicates unnecessary restrictiveness through the technical specification in question. First of all, the “programme with 3 phases” and “programme with 1 sterilization phase” are not standard features.
Please modify the technical requirement from this item by stating that the sterilizer should have at least 3 sterilization cycles, with the duration of the fastest cycle being 40 minutes and the slowest cycle being 60 minutes, which fits with what most manufacturers offer.
- c) In item 15 you state that the sterilizer should have a touch screen with the minimum diagonal of 10”. Since the sterilizer is not in frequent use, but only for several cycles per day, it is clear that the requirement for the extremely large diagonal is unnecessary. Larger diagonals are used with sterilizers with more frequent interactions between the user and device, which is the case with steam sterilizers in central sterilizations.
Please take our request into account and, in order to increase competition, accept the devices with touch screens with the minimum diagonal of 7”.

- d) Items 16-19 define the types of medical element which can be sterilized in the plasma sterilizer, but in the manner which can significantly limit competition. In addition, item 18 defines the length of lumen at 4.000 mm, which makes no logical sense, since there are no medical elements that long. Finally, it is required that 10 lumens (long hollow elements) can be sterilized in each cycle. This requirement is also not logical, since the sterilizer will be used for a couple of cycles per day, i.e. it is practically unlikely that the beneficiary will have the need to sterilize as many as 30–50 endoscopes on a daily level (3–5 cycles with 10 endoscopes each).

Please take our request into account and, in order to increase competition and define the needs in a realistic manner, redefine your requirement, i.e. define the type of the medical elements and their number simply as: “Sterilizer can also in certain cycles sterilize a larger number of lumens at the same time. The sterilizer can treat rigid endoscopes as long as 500 mm (internal diameter of 1 mm or more) and flexible endoscopes as long as 1.100 mm (internal diameter of 2 mm or more).”

- e) Item 25 specifies the external dimensions of the sterilizer as max. 1055 x 1690 x 1080 (width x height x depth). The dimensions are obviously specified to the tenth part of the centimetre, which can indicate that this is a specification typical for one manufacturer. In addition, the defined height is unrealistically low, since the device is placed on wheels (the wheels increase the total height) and since there is enough space in the room to install devices with larger dimensions. Please redefine your request concerning the dimensions of the device in question. We suggest defining the dimensions as: max. 1100 x 2200 x 1100 mm, which doesn't additionally limit competition. We'd like to point out that width and depth of most of the products on the market are significantly lower than our previous suggestion.

Answer 9:

- a) The Purchaser considers that this position is justified because the temperature variation during the cycle never exceeds more than 1 or 2 ° C, and this range is considered to be sufficient.
- b) The Purchaser considers that this position is justified because the total cycle time is not sufficient to qualify the type and purpose of the cycle. The number of individual phases of sterilization (absorption of the vaporized hydrogen peroxide solution) is critical and as such determines whether surface sterilization or sterilization of shorter or longer lumens will be performed.
- c) The Purchaser considers that this position is justified because as with automatic steam sterilizers, the plasma sterilizer also has an identical minimum diagonal of the touch sensitive monitor. Observation that for the monitoring of the operation of the automatic steam sterilizer is necessary the more frequent interaction between the user and the device is unfounded.

- d) The Purchaser considers that this position is justified because during the working day in the plasma sterilizer will not only sterilize long lumens but other thermolabile materials. The amount of lumen per sterilization allows us to use the device in accordance with the purpose and to refer to the consumable material (sterilant agent) economically using optimal cycles for each type of thermolabile materials. The Purchaser clearly determined the length of the lumen that could be sterilized, because in the period of exploitation, the procedures and the use of lumens of larger lengths will certainly be improved, which already exceed those listed in the proposal of the potential bidder.
- e) The Purchaser considers that this position is justified because it gave maximum installation measures for the plasma sterilizer in accordance with the available space.

Question 10:

“2.4.3 Duplex softener”

- a) In item 1 it is said that the device has the capacity of exactly 1.000 lit/h. A device with a slightly higher capacity can only bring benefits for the use.
Please redefine your requirement by requiring the capacity of min. 1.000 lit/h.
- b) Item 4 precisely defines the type and the size of the column (8x35). Since the previous item defined the filling as 20 litres in each column, and therefore the ion exchange capacity of each of the column, this is a completely unnecessary limiting of competition through requiring the exact dimensions of the column.
Please completely remove the requirement from item 4.
- c) Items 8–10 precisely define the dimensions of the entry and exit lines. Since the device itself is set for a certain flow, its connections are factory-set to support that flow. In that regard, it is technically unfair to define the precise dimensions of connections, since different manufacturers may have different solutions, with meeting the required capacity.
Please make a correction in your requirement by stating that you will accept devices with water entry and exit connections of min R½”. This way you increase completion and do not lose on the work performance.
- d) Item 12 defines the volume of the tank receiving the permeate (RO purified water). The volume of 200 litres is unusually high, since such a system of 2 sterilizers and 2 washing machines will not use more than 100 litres per hour. The tank’s task is only to provide the sufficient amount of water at peak consumptions, which means that in practice a tank of around 50 litres could be sufficient. Specifying a large tank can favour a manufacturer offering precisely such a tank for RO water with the capacity of 200 litres as a part of their standard model.
Please make a correction in your requirement by stating that you will require a tank for RO water with the capacity of min. 50 litres.
- e) Item 13 defines the volume of the reverse osmotic module. This is a highly unusual requirement, because the capacity of the RO device is not defined anywhere, while on the other hand the reverse osmotic modules are not defined in practice by the volume of their housing, but by their dimensions.

- Please completely remove this requirement or change it to be in line with the way it is defined with the softener in item 1: "Production capacity: min 100 lit/h"
- f) Items 14–16 precisely define the dimensions of the entrance and exit connections. Since the device itself is set for a certain flow, which meets the beneficiary's needs, its connections are therefore factory-set to support that flow. In that regard, it is technically unfair to define the precise dimensions of connections, since different manufacturers may have different solutions, with meeting the required capacity.

Please make a correction in your requirement by stating that you will accept devices with water entry and exit connections of min R $\frac{3}{8}$ ". This way you increase completion and do not lose on the work performance.

- g) In item 24 it is said that the device has the microprocessor control, and that it switches into sleep mode after completion. This requirement is not precise. What does "completion" refer to? Such devices generally work in their full capacity as long as there is a need for it, i.e. as long as the consumers need purified water. The device will therefore turn on and off when needed, but there is no clear distinction between the start and completion of their work.

Please make a correction in your requirement in item 24 by completely removing the part in the brackets, i.e. remove the requirement for any kind of sleep mode.

Answer 10:

- a) The Purchaser considers that this position is justified because this is the calculation of the flow of water that is necessary for the functioning of the device in central sterilization.
- b) The Purchaser considers that this position is justified because these are the standard dimensions of the columns that are in use on the market.
- c) The Purchaser considers that this position is justified because from the place of installation of this system, treated water is separately directed to consumers and by placing smaller connections it would jeopardize the supply of water to consumers at a greater distance and distant parts of the same diameter.
- d) The Purchaser considers that this position is justified because the calculated water consumption during the final wash in the washing and disinfection machines with the steam generator is quite high and certainly exceeds 100 liters per hour.
- e) The Purchaser considers that this position is justified and clearly defined the characteristics of the RO module.
- f) The Purchaser considers that this position is justified because from the place of installation of this system, treated water is separately directed to consumers and by

placing smaller connections it would jeopardize the supply of water to consumers at a greater distance and distant parts of the same diameter.

- g) The Purchaser considers that this position is justified because the period of inactivity of the RO device is considered to be sleep mode. The moment the device receives a signal that the production of RO water is needed, it switches to active mode and starts the necessary components and circuits of the device.

Question 11:

“2.4.4 Washer Disinfector”

- a) In item 2 it is said that the device performs chemical disinfection. This is probably a mistake since these devices perform THERMAL disinfection. The requirement from item 10 stating the extremely high power which is typical when water needs to be heated to over 90°C for thermal disinfection also supports this assumption. In addition, in item 13 there is a requirement for disinfection to be performed according to the A0 principle, which is usual for thermal disinfectors. Please change the requirement so that it says that the device is used for washing, thermal disinfection and drying of medical instruments.
- b) Item 5 defines the maximum work flow of the pump for recirculation of water of min. 620 lit/h. For this type of device anything over 450 lit/h is an unusually large flow for the recirculation pump. Manufacturers have different solutions, so with some of them the same washing effect is achieved with significantly lower flows. Please make a correction in this requirement by accepting devices with the maximum work flow of the pump of 450 lit/h.
- c) Item 7 requires the foam control feature. Since this feature is not typical for most manufacturers, its justification is questionable in terms of limiting competition. In addition, such devices usually use liquid detergents which do not foam, so there is a question of functionality of the foam control feature. This option makes sense only with devices with the risk of occurrence of foam, as it is the case with the use of powder detergents, which is definitely not the case here. Please completely remove the requirement from item 7 as unnecessary and limiting in terms of increasing competition.
- d) Item 9 requires a drain valve with the high capacity of as many as 5 litres per second. Every manufacturer calculates their components based on certain set parameters. It is very ungrateful to define the throughput capacity of the drain valve as an important requirement, since the speed of draining is in no way a crucial factor in determining the important operating parameters. For example, a device spends 20-odd litres of water per a washing phase, which means that draining with the valve with throughput capacity of 2 litres per second will be done in only 10 seconds. Finally, there is a question of the throughput of the drain sewage system receiving the waste water. High throughput of the drain valve makes no sense unless the drain sewage system can receive so much water in such a short time span. Please completely remove the requirement for the drain capacity of 5 lit/sec, because it is an unnecessary and very restrictive requirement.

- e) Item 10 defines the electrical power of the water heater at 15–20 kW. Certain technical solutions also allow for the use of heaters with lower power, without losing the efficiency in work, i.e. without unnecessarily prolonging the length of the cycle, while on the other hand reducing the load of the electrical installations. Please make a correction in this requirement by stating that the required water heater power is 8 to 15 kW, which suits most of the manufacturers.
- f) Item 11 defines the power of the ventilator of the air heater for instrument drying, as the capacity of 300 m³/h. The requirement for the ventilator capacity isn't particularly important as long as the air heater has the sufficient power. Specifically, certain solutions used by certain manufacturers, like the manner of directing the heating air, enable achieving efficient drying with a significantly lower capacity of the ventilator. Specifying the high capacity can be interpreted as favouring one manufacturer who achieves their drying effect exclusively with high air flow of the ventilator. Please make a correction in the requirement from item 11, by completely removing the requirement for the ventilator capacity.
- g) Item 12 defines the type of the control panel as "touch panel" with LCD display. The term "touch panel" is not completely clear, because this is obviously not a touch screen. Since the complete control of the device operation is done on the unloading side, the type of the control panel on the loading side is completely irrelevant. Please make your requirement more specific, by accepting devices with control panels consisting of the LCD screen and functional keys on the unloading side, and remove the requirement specifying the type of panel on the loading side.
- h) Item 20 specifies the external dimensions of the device. The maximum allowed height is 1.850 mm. Since there is enough free space to install significantly taller devices, we believe it would be desirable, in order to increase competition, to increase this value. Please make a correction in your requirement and allow devices with the height of max. 2.000 mm.

Answer 11:

- a) The Purchaser accepts the suggestion and states that the device is used for washing, thermal disinfection and drying of medical instruments.
- b) The Purchaser considers that this position is justified because the operating flow of the pump is directly related to the quality of the washing or rinsing of the instruments.
- c) The Purchaser considers that this position is justified because the control of foam creation eliminates the possibility of damage to the pump and inefficient flow due to incorrect dosing or use of an inadequate product.
- d) The Purchaser considers that this position is justified because fast drainage is just one of the crucial factors for washing and disinfection machines both in normal exploitation and in cases of emergency, when rapid and complete drainage is required.

- e) The Purchaser considers that this position is justified because it is defined for the sake of different technical solutions and has put the range that implies as much as 25% lower power of the heaters than the maximum.
- f) The Purchaser considers that this position is justified because with proper air heating the very capacity of the heated air is crucial in a quality and efficient air intake and no air guidance can provide uniform drying throughout the whole volume of the chamber.
- g) The Purchaser considers that this position is justified because it clearly specified the type of panel that the device should have, and that is certainly not an LCD screen with function keys. Regarding the control panel from the cleaner side and its significance, the customer also remains at his requirements.
- h) The Purchaser considers that this position is justified because each washing and disinfection device emits a certain amount of heat, especially during drying, which, according to the laws of physics, moves from a lower to a point of maximum height. In order to ensure correct removal of the heated air, and increase the volume of the heated air, and therefore reduce its temperature in the space above the device, it is necessary to provide as much space for such operation.

Question 12:

“2.4.5 Cloth cutting machine”

- a) In item 1 it is said that the device has the knife with the diameter of 100 mm. In order to increase competition it is better to give a range than an exact value. Please make a correction in the requirement from item 1 and allow devices with the knife diameter in the range of 100–125 mm.
- b) In item 2 you state that the device should use single-phase power supply 220V, 50 Hz. Certain devices work with the power supply of 3x380V, 50 Hz, which is better than the listed requirement in terms of achieving the result of textile cutting and the device motor load.
Please make a correction in the requirement and accept devices using either the single-phase power supply 220–230V, 50 Hz, or the three-phase power supply of 3x380–400V, 50 Hz.
- c) In item 3 you state that the power of the motor must be 100W. This is a very rigorously set requirement and the power is unrealistically low. One must not forget that this device should also have the ability to cut thicker layers of gauze, which is why greater power is simply necessary for comfort in work.
Please make a correction in the requirement and require devices with the max. power of 400W, which increases competition.
- d) Item 4 defines the knife capacity at 25 mm/1” (second). This requirement doesn’t make much sense, because the speed (capacity) of cutting will depend on both the type of the material cut, and on the skills of the operator.

Please completely remove this requirement defining the “capacity”, as by itself it doesn’t make any sense.

Answer 12:

- a) The Purchaser considers that this position is justified because the required knife diameter is the standard dimensions.
- b) The Purchaser considers that this position is justified because there is no possibility of bringing the three-phase connection at the intended use point, and the use of extension cables is not allowed.
- c) The Purchaser considers that this position is justified because the use of modern engines and transmission reduces engine power multiple times and therefore its consumption.
- d) The Purchaser considers that this position is justified because the knife capacity is a technical feature that defines every device for this purpose.

Question 13:

“2.4.6 Trolley for transport of sterile material“

- a) In item 5 it said that the trolley should have wheels with diameter of min. 160 mm which “do not leave traces” with several more insufficiently clear requirements. The 160 mm diameter is quite big and unusual for this type of equipment, which significantly reduces competition.
Please make a correction in the description, i.e. simplify it by saying, without specifying the minimum wheels diameter, that 4 wheels are required, with at least 2 of them with brakes, which is how they are usually made.
- b) Item 6 gives the maximum dimensions of the trolley in quite a restrictive way, which is not necessary taking into account the defined capacity of the trolley (6 STU).
Please specify less restrictive dimensions of the trolley, for instance maximum of 1000 x 800 x 1600 mm.

Answer 13:

- a) The Purchaser considers that this position is justified because large wheels provide easier rolling on areas that are not completely even, and as our hospital is pavilion-type hospital, the encounter with curbs and other unevenness during manipulation is often.
- b) The Purchaser considers that this position is justified because the dimensions given in the specification are made so as to allow unhindered communication in all places in the hospital where the material is to be delivered.

Question 14:

“2.4.7 System for tracking and tracing in the system of sterile instruments supply“

- a) In item 12 it is said that “every place of use” should have the adequate hardware. If possible, please clarify where the places of use are located and how many of them there are, or if this is left to manufacturer’s choice.
- b) Items 10 and 11 define that the system should also cover the delivery and the place of use of the instruments. It has been proven in practice that such a system is too complex and requires a significantly long implementation. From practical reasons it is much better to envisage a system covering the movement of instruments from their entry into central sterilization to their exit. It is also desirable to envisage possible future upgrades of this system. Please make a correction in this part of the technical requirements, and completely remove the requirements from items 10 and 11.
- c) In item 16 it is not defined clearly enough that the system has the possibility to recognize the missing and insert new elements into the system. We assume that what is meant is that the system allows certain worn out instruments to be taken out of the system and new ones inserted into the database. Please either remove this requirement or reword it by giving a clear explanation that the system is expected to be able to remove the existing and insert new elements.

Answer 14:

- a) The Purchaser accepts the suggestion and states that the system should be incorporated in the following points: reception, washing and disinfection, packing, sterilization, delivery and place of use of material.
- b) The Purchaser considers that this position is justified and clearly predicted that there is “the place of use of the material“in order to be able to determine the phase in which the material is in the moment of the search.
- c) The Purchaser considers that this position is justified because this characteristic allows the administrator to update sets’ information when there is a change in their content by adding, taking out, or combining.

Question 15:

15. “2.4.8 General table”

- a) In item 4 it is said that the general table should be min. 700 mm wide. These tables are made with widths from 650 to 750 mm, depending on the practice in different countries. In order to increase competition, it would be desirable to accept tables in a certain range of their width. Please make a correction in technical documents by allowing offering of tables with the width in the range 650–750 mm.

Answer 15:

- a) The Purchaser considers that this position is justified from the aspect of real needs and available space.

Question 16:

“2.4.9 Height adjustable packing table”

- a) Item 3 requires that the table can be pre-set to at least 4 tabletop heights. At the same time, item 2 requires the feature of adjusting the tabletop height by push buttons. If the table has the feature for adjusting the tabletop height to any position in a certain range, then there is no use for having pre-set positions. Moreover, setting it to any position is a more comfortable solution. Please make a correction in this requirement and also allow tables with the possibility of pre-setting min. 4 tabletop heights, or setting the table in any position in the available height adjustment range.
- b) Item 4 requires that the tabletop is made of stainless steel or better material. Since these tables are used in well-lit rooms and the employees spend lengthy periods of time sitting at the table, it would be desirable for the tabletop to be made of some “warmer” material, with reduced light reflection. Please make a correction in this requirement by allowing offering of tables with tabletops made of stainless steel, HP laminate or similar material suitable for use in central sterilizations.
- c) In item 5 it is specified that the table should have aluminium columns for bearing the shelves. These elements are usually made of stainless steel, since most of the other elements are made from stainless steel. Please make a correction in this requirement from item 5 and allow tables with columns for shelves made of stainless steel.

Answer 16:

- a) The Purchaser considers that this position is justified and that the pre-defined positions exist, so that without additional checks and adjustments, positions already defined by the operator and the purpose of the table could be achieved.
- b) The Purchaser considers that this position is justified because this determines the material of the table suitable for maintenance, prevention of interaction with cleaning and disinfection agents, all with the purpose of preventing the spread of hospital infections.
- c) The Purchaser considers that this position is justified because the columns for carrying shelves made of aluminum reduce the total weight of the table, and do not affect the firmness and maintenance itself.

Question 17:

“2.4.10 Instrument washing sink”

- a) In item 6 it is said that the table should have the width of min. 700 mm. Such tables are usually made in widths from 650 to 750 mm, depending on the practice in different countries. At the same time it says that the table should have the height of 850 mm. This is very unusual because all other tables required for the central sterilization in this tender have the height of 900 mm. In order to increase competition, it would be desirable to accept tables in a certain range of their width, and to align the height with the other tables.

Please make a correction in the documentation by allowing offering of tables with width in the range 650–750 mm, and by requiring the height of the table (from the floor to tabletop) of 900 mm.

Answer 17:

- a) The Purchaser considers that this position is justified from the aspect of real needs and available space.

Question 18:

“2.4.11 Linen inspection table”

- a) In items 2 and 3 it is said that the linen inspection table should have at least 4 tubular lights. We'd like to highlight that what's usually used are LED lights which don't necessarily have to be in the form of tubular lights. Insisting on tubular lights can significantly, and without any justifications, reduce competition. Please make a correction in the requirements in items 2 and 3 and allow tables either with tubular lights or with LED lights in another form, with removing the requirement defining the number of lights in the case of LED lights.

Answer 18:

- a) The Purchaser considers that this position is justified from the aspect of even illumination with minimal heat energy that could damage it, blur the transparent part of the table and reduce the effect of light.

Question 19:

“2.4.12 Paper trolley”

- a) Item 3 defines that the paper trolley should also have a bottom shelf made of stainless steel. This trolley should not have any shelf by its nature, because it can only make positioning of the paper placed over the bearing frame more difficult. Trolleys with the bottom shelf are very rare, which can be interpreted as a requirement limiting competition without any essential need. Please make a correction in this requirement and accept paper trolleys without the bottom shelf, i.e. completely remove the requirement from item 3.

Answer 19:

- a) The Purchaser considers that this position is justified because the shelf in the lower zone prevents the paper from falling onto the floor during manipulation and its contamination and washing with fibers or other materials.

Question 20:

“2.5.3 Wall brackets”

- a) In item 5 it is said that the length of the vertical brackets should be exactly 700 mm, and the distance between the hooks on the vertical brackets should be 345 mm. These are very rigorous requirements concerning less important technical characteristics.

Please make a correction in the requirement from item 5 and also accept brackets with length in the range of 700 mm $\pm 5\%$ and with the distance between the hooks in the range of 350 mm $\pm 5\%$.

Answer 20:

- a) The Purchaser considers that this position is justified because these dimensions enable optimal layout and number of the baskets as well as their manipulation.

Question 21:

“2.5.4 Fixed solid shelf system”

- a) Item 4 gives the external dimensions of the solid shelf system as 1520x460x1830 mm $\pm 5\%$. Defining the tenth part of the centimetre as the benchmark measure is a very limiting factor for most of the bidders. Solid shelf systems of this kind intended for storing STU baskets and boxes which are required by the Purchaser in other parts of this lot, are usually made with various shelf widths, which are usually rounded to values such as 400mm, 500mm, 600mm. Both the length and height of the fixed solid shelf systems are usually defined as rounded values, such as 1000mm, 1200mm, 1500mm, 1800mm.
Please make a correction in your requirement and allow fixed solid shelf systems with widths in the range 400-600mm.

Answer 21:

- a) The Purchaser considers that this position is justified because external cabinet measures are given in order for internal, "clean" measures to be optimal for accommodating materials placed in baskets and boxes of standard dimensions. The larger depth cannot be used because it would violate the possibility of unhindered passage and manipulation of material.

Question 22:

“2.5.5 Magnifying lamp”

- a) Item 4 requires that the device has one fluorescent lamp, max. 22 W. Modern solutions use LED lights with the adequate layout with two or more lights which achieves the same effect of lighting with the equal or lower power.
In order to increase competition, please also accept devices having more than one light with the max. power of 30 W, which represents improvement compared to your original requirement.
- b) In item 5 it is said that the lens should be a 4-diopter magnifier. In most of the cases lenses for such uses go up to 3-diopter magnifier.
In order to increase competition, please allow offering of devices with 3-diopter or higher.
- c) In item 7 you state that the lamp should have two segments (arms), with one of them being 430 and the other 400 mm long. One part of manufacturers specifies the total length of the two arms which defines the maximum length of positioning of the lens on the arms.
In order to increase competition, please define the maximum length of both segments together: Two arms of total length min. 800 mm.

- d) Item 8 gives the possible angles for setting the arms of the lamp. These values are rarely specified by manufacturers in their brochures and as such they are less important, since the purpose and the acceptable level of flexibility of settings can already be determined from the photograph. Specifying these values can be interpreted as restrictive.

In order to increase competition, please completely remove the specified angles for setting certain segments of the lamp.

Answer 22:

- a) The Purchaser considers that this position is justified because uniform lighting on the entire surface of the light source is a very important category that cannot be achieved with two separate sources. The power of the light is standard for this purpose.
- b) The Purchaser considers that this position is justified because diopter +4 provides a larger magnification which is certainly benefit of this characteristics.
- c) The Purchaser considers that this position is justified because using two hands of approximate dimensions, allows a better mobility and greater radius of movement of the device.
- d) The Purchaser considers that this position is justified because it shows the possibility of positioning the lamp in certain positions that are typical for the purpose of central sterilization.

Question 23:

“2.5.6 Spray gun”

- a) In item 6 you state that the gun should be made of stainless steel with heat insulated grip. In most of the cases, in order to reduce the weight of the element, the hand-held spray gun is usually made mostly of aluminium. This drastically facilitates manipulation of the gun.
Please change this requirement and rephrase it in such manner to allow spray guns made of stainless steel, or aluminium, or completely remove the request from item 6 concerning the material.

Answer 23:

- a) The Purchaser accepts the suggestion of the potential bidder and allows the spray gun to be made of stainless steel or aluminum.

Question 24:

“2.5.7 Overhead shower”

- a) From the description of this device it cannot be positively concluded where this device should be placed and how it should be used, which indicates that only the manufacturer having such a device in their offer can recognize this device from the description. For example, item 2 says that the device is operated automatically by pulling the hose downwards.
Please make a partial clarification of this requirement, and allow the devices operated by simply pressing the handle on the shower (at the end of the water hose), which still retains the possibility of one-handed operation (which was obviously the objective here).
- b) Item 4 states that the device should have the option of mixing water with two taps. Modern shower systems have different types of faucets for mixing warm and cold water, which very often do not have separate taps.
In order to increase competition, please make a correction in your requirement and allow using showers which achieve mixing of warm and cold water in any way (not necessarily with separate taps), or completely remove the requirement setting the manner of mixing water from item 4.
- c) Item 5 defines the maximum dimensions of this device. Specifying the external dimensions is of no functional significance. Only the total height of the device can be important for the beneficiary, due to the available space from the workspace to the ceiling. Also, the total length of the water hose can be important for the beneficiary. Specifying the exact dimensions which are not of functional significance with $\pm 5\%$ can be very restrictive and suit only one potential manufacturer.
In order to increase competition, please completely remove the requirement from item 5 concerning the maximum allowed dimensions, or leave only the total height of the device as max. 1250 mm as relevant.

Answer 24:

- a) It is positioned on the battery that is placed above the sink. It is activated by pulling the end of the shower towards the sink, for easier manipulation.
- b) The Purchaser accepts the suggestion of the potential buyer. Any solution for mixing of cold and hot water will be accepted.
- c) The Purchaser considers that this demand is justified, as the dimensions are determined in accordance to the needs and available space.

Question 25:

“2.5.8 Ultrasonic cleaning unit”

- a) Item 2 states that the capacity of the device should be min. 25 litres. This is a very vague specification, because such devices are placed on the work area, near the

sink, so extremely large dimensions can present a problem with space. In order to better utilize the space and reduce the energy consumption, it would be optimal to define both the range of the working capacity and the maximum dimensions of the device.

Please make a correction in your requirement and specify the required working capacity in the range 25-30 litres.

- b) Nowhere in the technical requirements have the important parameters for this type of device been defined, namely the temperature range and the option to set the time (duration) of the ultrasound cleaning.

Please make a correction in your requirement and require the option to set the working temperature in the range 40-80°C, and point out that the device should have the option of setting the duration of cleaning.

Answer 25:

- a) The Purchaser considers that this position is justified because it has been determined according to its minimum requirements for this type of device.
- b) The Purchaser considers that this position is justified because it has determined all the parameters needed to perform the required procedures on this type of device.

A handwritten signature in black ink, appearing to read 'U. Furia' or similar, with a stylized flourish at the end.