



**HEALTH ESTATES**

creating healing environments



**DHSSPS GENERAL DENTAL  
SERVICES QUALITY IMPROVEMENT  
SCHEME  
MODEL ENGINEERING  
SPECIFICATION (MES)  
SMALL STEAM STERILIZERS FOR  
SURGICAL INSTRUMENTS**

**NOVEMBER 2007**

# SMALL STEAM STERILIZERS FOR SURGICAL INSTRUMENTS

## DESIGN NOTES

### Scope

This specification is designed to be used for the purchase of small steam sterilizers that are widely used for medical purposes in healthcare environments such as general medical practices and dentistry. They are also used for materials and equipment that are likely to come into contact with blood or bodily fluids such as dental instruments. The very specific sterilizer loads used within these fields of application call for different performance requirements for the sterilization cycles and different corresponding test methods.

It is essential that the sterilizer and associated equipment is used only for the sterilization of the type of products for which it is designated. The choice of sterilizer, sterilization cycle or quality of services provided can be inappropriate for a particular load. Therefore the suitability of a sterilization procedure for a particular product needs to be verified by validation.

A small steam sterilizer is defined as an electrically heated, steam sterilizer which is unable to accommodate a standard sterilization module (300mm × 300mm × 600mm) and with a chamber volume not exceeding 60 litres.

### Specification Format

The specification is designed in modular form so that it can specify the number and type of sterilizers required whilst minimising any inapplicable information. The user of this specification will need to know the number of sterilizers required together with detailed information on the process cycles, load parameters and testing procedures involved.

Whilst the vast majority of information in the relevant Elements of Section will apply in all instances of procurement, the need is recognised to detail specific items to the site's or User's requirements. These details are to be stated in Section D.

The Tenderer will complete the details in Section D to supply information on the sterilizers required to the Purchaser. This Tender return will comprise the whole of Section D together with any other requested relevant details.

### Assembly of Specification

When issued to invited Tenderers, this Section shall contain **ONLY** the following:

- I. Part C Index.
- II. Part C Element 01: References.
- III. Part C Element 02: General.
- IV. Part C Element 03: Technical.
- V. Part C Element 04: Test Methods.
- VI. Part D Completed by the Purchaser as required and sections to be completed by the Tenderer as requested.
- VII. Drawings and supporting information.

### Section D

## SMALL STEAM STERILIZERS FOR SURGICAL INSTRUMENTS

The following Clauses of Section D are to be completed by the GDP prior to seeking tenders. Some of these may not apply and the GDP should refer to the specific guidance for completion of the specification.

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All instances of choice in the above Clauses are cross-referenced in the relevant Clause in Section C. It is the responsibility of the GDP to check that all Clauses of Section D requiring input from Section C are completed.

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The following Clauses of Section D are to be completed by the Tenderer:

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Part D of this specification allows the GDP to identify directly the number and type of sterilizers required.

100% standby may be required in a small unit that theoretically only needs one small sterilizer.

The sterilizer type and size mix may contribute to the utilisation factors required.

**End of Design Notes**

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### SMALL STEAM STERILIZERS

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# SMALL STEAM STERILIZERS FOR SURGICAL INSTRUMENTS

## SECTION C ELEMENT 01

### STANDARD REFERENCES

01

The materials, components and completed installations shall conform as applicable with the following Standards, including all amendments, current at the time of tendering. Construction products should comply with European Standards and Technical Specifications (ESTS). Wherever reference is made to a British Standard a corresponding ESTS (generally ISO series) shall be equally acceptable.

Where available all materials, equipment etc forming part, or whole, of the services specified in the Contract, should be obtained from BS EN ISO 9000 - "Quality Assurance" certified manufacturers and or EC equivalent.

The latest dates of standard references are given at the time of issue of this Section.

### BRITISH, EUROPEAN AND INTERNATIONAL STANDARDS

|                        |  |
|------------------------|--|
| BS 759                 | Valves, gauges and other safety fittings for application to boilers and piping installations for and in connection with boilers. |
| Part 1:1984            | Specification for valves, mountings and fittings.  |
| BS EN 60601            | Medical electrical equipment. General requirements for safety.   |
| BS 1041                | Temperature measurement.   |
| Part 2:                | Expansion thermometers.  |
| Section 2.1:1985(1992) | Guide to selection and use of liquid-in-glass expansion thermometers.  |
| Section 2.2:1989       | Guide to selection and use of dial-type expansion thermometers.  |
| Part 3:1989            | Guide to selection and use of industrial resistance thermometers.  |
| Part 4:1992            | Guide to selection and use of thermocouples.   |
| Part 5:1989            | Guide to selection and use of radiation pyrometers.  |
| Part 7:1988            | Guide to selection and use of temperature/time indicators.   |
| BS 1306:1975 (1990)    | Specification for copper and copper alloy pressure piping systems.   |
| BS EN 10088-1:1995     | Stainless steels – Part 1: List of stainless steel.  |
| BS EN 837-1:1998       | Pressure gauges. Bourdon tube pressure gauges. Dimensions, metrology, requirements and testing.                                  |

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|   |  |
|---|--|
| BS EN 60751:1996,<br>IEC 60751:1983     | Industrial platinum resistance thermometer sensors.  |
| BS EN 61260:1996,<br>IEC 61260:1995     | Electro acoustics. Octave-band and fractional-octave-band filters.   |
| BS EN 61010-02-041:1997                 | Safety requirements for electrical equipment for measurement, control and laboratory use. Particular requirements for autoclaves using steam for the treatment of medical materials, and for laboratory processes. |
| BS EN ISO 228-1:2003                    | Pipe threads where pressure-tight joints are not made on the threads. Dimensions, tolerances and designation.  |
| BS EN 1057:1996                         | Copper and copper alloys. Seamless, round copper tubes for water and gas in sanitary and heating applications.   |
| BS 3605                                 | Austenitic stainless pipes and tubes for pressure purposes.  |
| Part 1:1991                             | Specification for seamless tubes.  |
| Part 2:1992                             | Specification for longitudinally welded tubes.   |
| BS 3693:1992                            | Recommendations for design of scales and indexes of analogue indicating instruments.   |
| BS 3970                                 | Sterilizing and disinfecting equipment for medical products.   |
| Part 1:1990                             | Specification for general requirements.  |
| Partially replaced by<br>BS EN 285:1997 | Sterilization. Steam sterilizers. Large sterilizers.   |
| BS EN 1422:1998                         | Sterilizers for medical purposes. Ethylene oxide sterilizers. Requirements and test methods.   |

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## SECTION C ELEMENT 01

- BS EN 61010-2-043:1998, IEC 61010-2-043:1997  
Safety requirements for electrical equipment for measurement, control and laboratory use. Particular requirements for dry heat sterilizers using either hot air or hot inert gas for the treatment of medical materials, and for laboratory processes.
- BS EN 60073:1997,  
(2002) IEC 60073:1996  
Basic and safety principles for man-machine interface, marking and identification. Coding principles for indication devices and actuators.
- BS EN ISO 3740:2001  
Acoustics. Determination of sound power levels of noise sources. Guidelines for the use of basic standards.
- BS 4683  
Specification for electrical apparatus for explosive atmospheres.
- Part 2:1971 (1993)  
The construction and testing of flameproof enclosures of electrical apparatus.
- BS 4937  
International thermocouple reference tables. (10 Parts)
- Parts 1-8 replaced by BS EN 60584-1:1996, IEC 60584-1:1995 Thermocouples. Reference tables.
- Part 20 replaced by BS EN 60584-2:1993 Thermocouples. Tolerances.
- BS 5164:1975(1993) Specification for indirect-acting electrical indicating and recording instruments and their accessories.
- BS 5235:1975(1992) Specification for dial-type expansion thermometers.
- BS EN 60079-14:1997  
Electrical apparatus for explosive gas atmospheres. Electrical installations in hazardous areas (other than mines).
- BS EN 60079-10:2003  
Electrical apparatus for explosive gas atmospheres. Classification of hazardous areas.
- BS 5501  
Electrical apparatus for potentially explosive atmospheres (9 Parts).
- Part 1 partially replaced by  
BS EN 50014:1993 Electrical apparatus for potentially explosive atmospheres. General requirements.

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## SECTION C ELEMENT 01

Part 5 replaced by BS EN 50018:1995 Electrical apparatus for potentially explosive atmospheres. Flameproof enclosures 'd' and BS EN 50018:2000 but remains current.

|                                       |   |
|---------------------------------------|---|
| BS EN 61010                           | Safety requirements for electrical equipment for measurement, control and laboratory use.   |
| BS EN 61010-1:1993                    | General requirements.   |
| BS EN 61010-2-010:1995                | Particular requirements for laboratory equipment for the heating of materials.  |
| BS EN 61010-031:2002                  | Safety requirements for electrical equipment for measurement, control and laboratory use. Safety requirements for hand-held probe assemblies for electrical measurement and test. |
| BS EN 61010-2-032:1995                | Particular requirements for hand-held current clamps for electrical measurement and test.   |
| BS EN 61672-1:2003                    | Electroacoustics. Sound level meters. Specifications.   |
| BS EN 61672-2:2003                    | Electroacoustics. Sound level meters. Pattern evaluation tests  |
| BS EN 60688:1992                      | Electrical measuring transducers for converting a.c. electrical quantities to analogue or digital signals.  |
| BS EN 61326:1998,<br>IEC 61326-1:1997 | Electrical equipment for measurement, control and laboratory use. EMC requirements.   |
| BS EN 61000-4-3:2002                  | Electromagnetic compatibility (EMC). Testing and measurement techniques. Radiated, radio-frequency, electromagnetic field immunity test.  |
| BS 7671:1992 (2001)                   | Requirements for Electrical Installations (IEE wiring Regulations 16th edition).  |
| BS EN 13060: 2004                     | Small steam sterilizers.  |

# SMALL STEAM STERILIZERS FOR SURGICAL INSTRUMENTS

## SECTION C ELEMENT 01

### OTHER REGULATIONS, GUIDANCE AND CODES OF PRACTICE

Medical Device Regulations 2002. This updates and incorporates the Medical Devices Directives into UK law in 2002 under the Consumer Protection Act.

Guidance on Decontamination from the Microbiology Advisory Committee to the MDA, (The MAC Manual).

MDA Device Bulletin DB 9804 – The Validation and Periodic Testing of Benchtop Vacuum Steam Sterilizers.

MDA Device Bulletin DB 2002(06) – Benchtop Steam Sterilizers, Guidance on Purchasing, Operation and Maintenance.

MDA Device Bulletin DB 9901(NI) Note: Details of Device Bulletins (DB), Warning Notices (HN, SN etc.) are provided on the Health Estates, Northern Ireland Adverse Incident Centre (NIAIC) website: <http://www.dhsspsni.gov.uk/niaic>

Health and Safety at Work etc Act 1974. Partially amended by  
(application to environmentally hazardous  
substances) regulations 2002

Health and Safety at Work (Northern Ireland) Order 1978.

Health and Safety at Work Order (Application to Environmentally Hazardous Substances) Regulations (Northern Ireland) 2003. Note: The HSENI web site <http://www.hseni.gov.uk> provides information on Northern Ireland Health and Safety legislation and codes of practice.

Manual Handling Operations Regulations 1992.

PD 5500:2003 Specification for unfired fusion welded pressure vessels.

Pressure Equipment Directive (97/23/EC)

Pressure Equipment Regulations 1999.

Pressure Systems Safety Regulations 2000.

The Electricity at Work Regulations 1989.

Electricity at Work Regulations (Northern Ireland) 1991.

Health Technical Memorandum No 2010 – Sterilization.

Health Technical Memorandum No 2031 – Clean Steam for Sterilization.

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## SECTION C ELEMENT 01

Hospital Building Note No 26 - Operating Departments.

Health Facilities Note No. 30 – Infection Control in the Built Environment: Design and Planning.  
Health & Safety Executive document PM73.

National Physical Laboratory Symposium No 72 - "The Control of Noise" HMSO.

1999 Water Regulations for England & Wales.

Programmable Electronic Systems in Safety Related Applications:

Part 1 An Introductory Guide.

Part 2 General Technical Guidelines  
Health & Safety Executive Publications, HMSO 1987.

British Pharmacopoeia 2002.

Spongiform Encephalopathy Advisory Committee (1998) “Transmissible Spongiform Encephalopathy Agents: Safe Working and the Prevention of Infection” Advisory Committee on Dangerous Pathogens(ACDP) Spongiform Encephalopathy Advisory Committee (SEAC). The Stationery Office London, updates are available at the website <http://www.doh.gov.uk/cjd/tseguidance>

Control of Substances Hazardous to Health Regulations 1999 (COSHH).

**End of Element**

# SMALL STEAM STERILIZERS FOR SURGICAL INSTRUMENTS

## SECTION C ELEMENT 02

### GENERAL

02

#### 01 Scope

This Specification covers the supply and commissioning of small sterilizing equipment as defined below and in the following element(s). Details specific to the scheme or site are included in Section D which must be completed by the Tenderer and returned to the Purchaser as part of the completed Form of Tender.

If the Tender does not strictly comply with any or all of the details of this specification then the Tenderer shall declare in the Tender any such deviations together with reasons and full details of the alternative(s) offered.

A small steam sterilizer is defined as an electrically heated, steam sterilizer which is unable to accommodate a standard sterilization module (300mm x 300mm x 600mm) and with a chamber volume not exceeding 60 litres.

This specification covers the general requirements of small steam sterilizers designed to process non wrapped solid goods by the removal of air by steam displacement and wrapped or unwrapped, solid hollow and porous products incorporating an active air removal cycle, as defined in HTM 2010, to remove air from the load and the chamber.

At the time of writing, a European Standard for small steam sterilizers is being prepared. It classifies small steam sterilizers according to the types of load they are intended to process.

**Traditional (gravity displacement) small steam sterilizers** displace air passively from the chamber and load by steam generated within the sterilizer chamber or in a separate boiler within the sterilizer's casing. This is known as a 'Type N' cycle.

**Vacuum small sterilizers** have a pump or some other active method to remove air from the chamber and load. This type of air removal is found in 'Type B' cycles and some 'Type S' cycles.

They are described variously as vacuum benchtop sterilizers, benchtop porous load sterilizers, Type B sterilizers, or sometimes Type S sterilizers. Type S sterilizers should be used to process only the types of loads specified by the sterilizer manufacturer and it is not recommended that this type of Sterilizer be purchased by GDPs.

**Note:**

A different range of products will be processed in machines that incorporate active air removal, than in machines that incorporate air removal by steam displacement. Advice should be sought as to the appropriate machine according to the type of equipment to be sterilized as specified in part D.

# SMALL STEAM STERILIZERS FOR SURGICAL INSTRUMENTS

## SECTION C ELEMENT 02

### 02 Changes to Specification

The Purchaser shall be notified by the Tenderer in writing not less than 14 working days before delivery, of any intent to make changes from the offer on which the contract was awarded in respect of the specification and design of specified components, including any alterations resulting from changes in relevant standards. Where such changes take place, the Purchaser reserves the right to re-tender for the equipment.

### 03 Warranty Period

The Tenderer shall accept liability for defects for the sterilizer which occur within a minimum of a 12-calendar-month period after acceptance of the sterilizer. Satisfactory completion of the required/specified performance tests will be a prerequisite of acceptance.

This warranty period shall also include, but not be limited to, the following:

- software provided as part of the sterilizer control system.

The guarantee shall cover all parts and labour. This shall include those parts identified as replacement items in the maintenance schedule.

The length of the warranty period offered shall be specified in the return tender documentation.

The sterilizer shall be designed to withstand use for a minimum of 12 months without suffering failure other than those components identified on the maintenance schedule as requiring periodic replacement.

The repair and/or replacement of components (other than those specified within the maintenance schedule for periodic replacement) within the warranty period shall be at the Tenderer's expense (parts and labour). This includes making good, free of charge, any part found to be defective or showing signs of any weakness or undue wear as a consequence of faulty workmanship or materials.

Tenderers shall state within the section D21 the mean time between failures (MTBF) figure and guaranteed uptime for the sterilizer.

The supplier shall inform the purchaser of any recommended or required updates or upgrades to the software system with an option for purchase for a period of 5 years from acceptance of the sterilizer. This primarily refers to those updates/upgrades that provide "bug fixes" or are maintenance releases. Information on those upgrades that are providing added or new features is not compulsory unless requested by the Purchaser.

# SMALL STEAM STERILIZERS FOR SURGICAL INSTRUMENTS

## SECTION C ELEMENT 02

### 04 Manufacturer's Quality System

The manufacturer shall:

operate a quality system that conforms with the ISO 9000 series. If the manufacturer has both designed and manufactured the sterilizer, the quality system shall additionally conform with the BS EN 46001 (or BS EN ISO 13485). If the sterilizer has been manufactured to a design supplied by a third party the manufacturer's quality system shall also conform to BS EN 46002.

in either case, ensure that each supplier of accessories, fittings and other materials also operates an appropriate quality system and where appropriate the supplier shall comply with the relevant Essential Requirements of Medical Devices Regulations.

maintain manufacturing records and quality system documentation to be available for audit/inspection if requested by the purchaser.

### 05 Regulatory Requirements

The sterilizer shall comply with the relevant Essential Requirements of Medical Devices Regulations and shall be appropriately CE marked.

The Tenderer shall provide information on any relevant Standards or guidance documents used to demonstrate compliance with the Regulations.

### 06 The Process

**Note:**

For moist heat sterilization using steam as the sterilant it is essential that all surfaces to be sterilized are subjected to saturated steam at a predetermined temperature for a predetermined period of time. Proper steam penetration into the load and if applicable, into the individual items, therefore is essential. Steam penetration requires adequate air removal. The requirements listed below and the associated test methods address factors and parameters that may promote or inhibit steam penetration and therefore the efficacy of the sterilization process.

The MDA Device Bulletin DB 9804 recommends that the porous load type of [small steam] sterilizer should be equipped only with cycles for porous loads in order to minimise the possibility of an incorrect cycle being selected and consequent failure to sterilize the load.

Shall:

conform to the performance required in HTM 2010 Validation and Verification, and the MDA Device Bulletins DB 9804 and DB 2002(06)

provide serial advance through a sequence of stages. The stage in process to be clearly displayed on the front panel.

# SMALL STEAM STERILIZERS FOR SURGICAL INSTRUMENTS

## SECTION C ELEMENT 02

Shall:

conform to the performance required in HTM 2010 Validation and Verification, and the MDA Device Bulletins DB 9804 and DB 2002(06)

provide serial advance through a sequence of stages. The stage in process to be clearly displayed on the front panel.

adequately remove air with a method, suitable to the type of load to be processed, prior to the sterilization stage of the cycle.

allow a period of time for load and chamber equilibration not exceeding 30 seconds.

An equilibration time of 15 to 30 seconds is acceptable if:

- the rise of the theoretical steam temperature during the last 10 K of the heating stage is less than 8 K/min but greater than 1 K/min;
- during the last 10 K of the heating stage all temperatures measured in the chamber and the load, as well as the theoretical steam temperature, do not differ from one another by more than 2 K.

provide sterilization conditions according to, or alternatives which can be proven to be equivalent to, the time/temperature relationships of 134 C for 3 minutes and specified by the manufacturer and stated in the user instructions for each available sterilization cycle.

dry the load as required.

not distort damage or otherwise impair the utility of items processed through the machine where the manufacturer of the items to be processed has correctly indicated that they are suitable for processing in a steam sterilizer.

### 07 Facilities for Leak Testing

Shall, for sterilizers with a vacuum stage:

provide for an automated air leakage rate test cycle. This test cycle will operate between two pressures, one of which shall be equal to or lower than the lowest pressure during air removal and steam penetration considering all available sterilization cycles. An air leakage rate signified by a pressure change greater than 0.13 kPa/min shall result in a fault indication.

**Note:**

An air leak test for small sterilizers is described in the draft EN 13060, and DB 2002/06

**End of Element**

# SMALL STEAM STERILIZERS FOR SURGICAL INSTRUMENTS

## SECTION C ELEMENT 03

### TECHNICAL

03

#### 01 Operating Environment

The sterilizer shall:

be designed to perform in accordance with this Specification in environmental conditions within the range 5 °C to 40 °C and up to 80% relative humidity for temperatures up to 31 °C decreasing linearly to 50% relative humidity at 40 °C.

#### 02 Chamber Operational Life

The chamber shall:

be designed to withstand 36,000 operating cycles or last for 10 years whichever occurs first.

#### 03 Small Sterilizer Construction

Shall:

be in accordance with HTM 2010 “Design Considerations” unless otherwise instructed by this document.

have all components and surfaces free from sharp edges, burrs.

#### 04 Materials of Construction

Shall:

be selected so that the parts of the sterilizer which come into contact with the load, feed water and/or steam, are manufactured from materials which have corrosion, abrasion and thermal resistance properties not less than those specified for the 316 series of stainless steel (BS EN 10088 part 1).

be compatible with each other and the parameters of the process.

#### 05 Safety Devices and Safety Features

Shall:

include for the provision of a list of all safety devices together with their settings and methods of adjustment and testing.

include access codes for the purpose of maintenance and testing which are made freely accessible to the Purchaser.

be designed to fail in such a manner which does not cause a safety hazard to personnel.

# SMALL STEAM STERILIZERS FOR SURGICAL INSTRUMENTS

## SECTION C ELEMENT 03

prevent a safety hazard being caused by an error in the control or indication system.

have control, operation and safety of the door(s) fully complying with BS EN 61010, BS 3970 and HTM 2010.

have a pressure interlock independent of any microprocessor control system.

comprise a door and safety interlocking system which is independent of any microprocessor.

not permit access to the chamber with application of a force (without the use of a tool) of less than  $1000 \pm 100\text{N}$  to the door release mechanism during an operating cycle.

have means provided to prevent a new operating cycle being started, should failure in any part of the door interlock system occur.

prevent the operating cycle from being started until the doors are closed and locked. The doors to be capable of being unlocked and opened only after completion of an operating cycle, unless in a Type N machine where the machine is designed to dry with the door open.

provide an assessment to comply with the requirements of the relevant elements of the Pressure Equipment Directive (97/23/EC) and include the method of inspection to comply with the Health & Safety Executive document PM73.

include closing interlocks to ensure that:

- (a) heaters in the chamber cannot be energised or steam cannot enter nor be generated in the chamber until the door-locking members are engaged to an extent specified by the tenderer which is sufficient to withstand the design pressure;

and

- (b) compressed air or other gases cannot enter the chamber until the door-locking members are engaged to an extent specified by the tenderer which is sufficient to withstand the design pressure.

### **06 Cabinet, Frame and Panels**

Shall:

be provided with means to compensate for irregular surfaces.

be finished smooth, with an easy to clean surface.

give due regard to the means of access for component maintenance and general cleaning.

have maintenance access panels that are easily removed and re-installed but not without the use of a tool or key and properly secured.

for pass through machines, include a means of sealing between the machine and any installed partition.

# SMALL STEAM STERILIZERS FOR SURGICAL INSTRUMENTS

## SECTION C ELEMENT 03

### 07 Chambers

Shall:

be constructed to ensure that they are free draining and free from sharp internal corners which cannot be easily cleaned.

### 08 Door(s)

Shall:

have control, operation and safety fully complying with BS EN 61010, and HTM 2010.

have seals designed to be easily replaceable and facilitate cleaning the contact surfaces of the door seal without removing parts of the sterilizer that require removal using a tool.

incorporate a device to ensure that it can not be opened until the cycle is complete except for drying purposes.

when a fault is indicated, only be able to be opened after the sterilizer has been returned to a safe condition and then only by use of a key code or tool.

have means provided to prevent a new operating cycle being started, and not cause a safety hazard, should failure in any part of the door interlock system occur.

for double ended machines, not be possible for both doors to be open at the same time except for maintenance purposes.

### 09 Air Quality

Shall:

for air admitted to return the sterilizer chamber to atmospheric pressure following a vacuum stage, be filtered to an efficiency such that the filter shall retain not less than 99.5 % of particles greater than 0.30  $\mu\text{m}$ .

### 10 Pipework and Fittings

Shall:

be in accordance with BS 1306 (with amendments), BS EN 1057 and BS 3605 where applicable and be designed to allow the removal and maintenance of individual components and sections of pipework without distortion of any associated equipment.

be of a type that has been demonstrated not to support the growth of *Legionella pneumophila* when non-metallic materials are used for conveying water or aqueous solutions. WRc water fittings and materials directory should be consulted to identify approved products.

# SMALL STEAM STERILIZERS FOR SURGICAL INSTRUMENTS

## SECTION C ELEMENT 03

be resistant to 'de-zincification' when fittings, valves and other components manufactured from copper, gunmetal, bronze or similar materials which are intended to come into contact with water or aqueous solutions are used.

be manufactured from materials of a specification that will withstand the water quality as specified in HTM 2031.

have each valve clearly identified with a legend describing its function or clearly identified on an assembly diagram or with a unique code from which its function may be determined by reference to a pipework diagram.

be provided with means to ensure that all pipework, fittings etc. are free-draining so that when not in active use all tanks, connecting pipework etc can be drained dry.

### **11 Test Connections**

Shall:

be provided such that the sterilizer will have at least one standard test connection.

have a female pipe thread conforming to BS EN ISO 228-1:2003.

be at a point of easy access to the chamber and shall be clearly identifiable.

include branches behind the panel to every pressure gauge for the insertion of test gauges.  
Tees to be provided with leak-proof blanking off plugs and valves.

if connection is required to test or alter software parameters or diagnostics, have a separate panel connection for test requirements on all electrical outputs which are used as source signals for the processor in the form of connector-captive polarised plug and socket capable of a minimum of 500 matings without loss of contact efficiency.

### **12 Vacuum Pumps**

Shall:

be designed such that they cannot cause contamination of the load either during normal operation nor in the event of vacuum pump failure.

### **13 Usable Chamber Space**

Shall:

be stated in Clause D23 in litres including the dimensions and capacity of the maximum volume of load which the chamber is designed to accommodate on the loading equipment supplied with the sterilizer.

# SMALL STEAM STERILIZERS FOR SURGICAL INSTRUMENTS

## SECTION C ELEMENT 03

### 14 Chamber Furniture

Shall:

be supplied as appropriate to process the loads identified in D01.

### 15 Instrumentation – General

**Note:**

This specification does not preclude the use of microprocessor-based instruments and control systems providing the integrity of the safety systems is not prejudiced and information is not corrupted or lost.

Shall:

be such that the location of all sensors, whether connected to the controller or the process recorder, is appropriate and provides data which can be correlated to conditions throughout the chamber and load.

where more than one gauge or instrument is fitted in the same area, be of a uniform appearance. As an alternative to discrete instruments any or all of the required displays may be provided by a single display unit.

be located in a position where they can be viewed readily under normal operation of the sterilizer and their function identified.

be readable by normal or corrected vision from a distance of 1m and with a minimum illumination of 215 Lux.

for illuminated displays, the minimum character size shall be determined in accordance with BS EN 60073 for a viewing distance of up to 1 metre. For non-illuminated displays, e.g. LCD, the character height shall be not less than 10mm. Displays shall be mounted in such a manner that they do not reflect light to impair vision. Error messages (faults) shown on VDUs to be in an easily distinguishable form.

be supplied complete with all necessary power supplies, software, sensors and recording devices.

### 16 Measurement Systems (Including Control, Monitoring and Recording)

The minimum performance characteristics of the measurement systems shall meet or exceed the following requirements:

|             |               |                              |
|-------------|---------------|------------------------------|
| Temperature | Range         | 0°C to 150°C                 |
|             | Accuracy      | ± 1% over range 0°C to 100°C |
|             | Resolution    | 0.1°C or better              |
|             | Sampling rate | at least every 2.5 seconds   |

# SMALL STEAM STERILIZERS FOR SURGICAL INSTRUMENTS

## SECTION C ELEMENT 03

When fitted with cold junction compensation, the error shall be not more than  $.08^{\circ}\text{C}/^{\circ}\text{C}$  rise in ambient temperature.

|          |               |                                       |
|----------|---------------|---------------------------------------|
| Pressure | Range         | 100kPa to 1000kPa                     |
|          | Accuracy      | $\pm 2\%$ over range 100kPa to 500kPa |
|          | Resolution    | 1kPa or better                        |
|          | Sampling rate | at least every 2.5 seconds            |

|            |               |                                    |
|------------|---------------|------------------------------------|
| Pressure   | Range         | 0kPa to 15kPa                      |
| (Leak rate | Accuracy      | $\pm 1\%$ over range 0kPa to 15kPa |
| Testing)   | Resolution    | 0.1kPa or better                   |
|            | Sampling rate | at least every 2.5 seconds         |

where digital pressure indicators are used for door safety interlocks, an additional mechanically actuated indicator will be required.

Measurement instruments shall:

be adjusted to read identical pressures at calibration where two instruments are connected to measure pressure from the same source.

in the case of vacuum instruments scaled in absolute pressure units, be barometrically or temperature compensated and suitable for operation either when exposed directly to steam at 2.8 bar a., or when connected to the chamber via a siphon tube or an automatic isolation valve and vent.

incorporate a means of zero and span adjustment for setting on site, so arranged that authorised personnel can make the adjustment without having to remove the instrument from its case or dismantle the instrument.

**Note:**

A common sensor may be used for the indicator and controller whenever a recorder is fitted. It is permissible to have a common system for indication, control and recording providing a minimum of two sensors are used and the system is self-monitoring such that any error in the measured temperature which is in excess of the limit specified above results in the indication of a fault.

### 17 Monitoring and Recording Systems (Process Verification) - General

Shall:

be fitted to monitor and record the key variables of the operating cycle either independently or as part of the control system as required in clause D13.

be traceable to the production/batch load and/or instrument tray.

# SMALL STEAM STERILIZERS FOR SURGICAL INSTRUMENTS

## SECTION C ELEMENT 03

monitor and record the variables listed below:

- Date and time
- Sterilizer ID
- Batch number or cycle number
- Pass/Fail indication
- Where a vacuum stage is utilised:
  - Minimum vacuum achieved, number of pulses and stage time
  - Stage time
- For sterilizing stage:
  - Time above sterilizing temperature
  - Maximum temperature, Minimum temperature
  - Stage time

including sensors, amplifiers and A to D (Analogue to Digital) converters, and have an accuracy, resolution and response time not worse than the performance specified in clause C03.16.

if specified in clause D14, provide a clear indication when process variables are outside the set limits previously validated either by means of independent alarms or through an appropriate interface with the control system.

provide a visual display in real-time to the operator during the operating cycle either locally or via a computer.

if required as specified in clause D14, record the data electronically in a format suitable for periodic transfer to a Personal Computer. The data storage system shall hold sufficient data to record the data from not less than 5 days of continuous operation of the sterilizer and incorporate facilities for back-up and security of stored data. The manufacturer to supply documentation, sufficiently descriptive, of the interface and file protocol requirements to permit the transfer or to supply a complete software system for viewing, storing and analysis of the data.

include timers with an accuracy of  $\pm 2.5\%$  for periods up to 5 minutes and for periods above 5 minutes of at least  $\pm 1\%$ . This shall also apply to the recorder chart speed and digital printouts.

### **18 Monitoring and Recording Systems (Process Verification) – Watchdog Systems**

Shall:

where no independent monitoring system is specified, and where attainment of process values may affect the safety of the machine or effectiveness of the process, determine those measurement from more than one sensor. Where the measured values from such sensors exceed the tolerance level set by the manufacturer and verified during the performance validation testing, a fault condition is to be initiated.

# SMALL STEAM STERILIZERS FOR SURGICAL INSTRUMENTS

## SECTION C ELEMENT 03

### 19 Monitoring and Recording Systems (Process Verification) – Hard Copy Print Out

Shall:

be either a chart recorder, analogue printer, digital printer or any combination of these whenever specified in clause D13.

if a chart recorder is specified, be provided with strip charts not less than 90mm wide and scaled from left to right for increasing variables. The scale of the chart to be used should enable all variables to be plotted to at least maximum alarm values.

include timers with an accuracy of  $\pm 2.5\%$  for periods up to 5 minutes and for periods above 5 minutes of at least  $\pm 1\%$ . This shall also apply to the recorder chart speed and digital printouts.

if a printer is specified provide for hard-copy print-out from data which has been taken from a sampling rate for each channel of pressure and temperature of at least 2.5 second intervals. Print out to occur as the cycle proceeds or at the end of cycle and include for faults to be printed.

be located as specified in Clause D13, the tenderer to state the interface type.

include the following control command facilities: list, form feed, line feed, carriage return, print, and either inverted print, expanded print, multi-colour or multi-emphasis print quality.

remain legible for 10 years after printing and be photocopyable.

be traceable to the production/batch load and/or loading basket.

have a self test facility incorporating line feed.

have a minimum width of 35 characters. Characters not relevant to the specified data to be omitted.

produce a printed record which, when illuminated within the range 200 lux to 400 lux and viewed with normal or corrected vision, will be clearly legible at a nominal viewing distance of 25cm.

provide operator sign off area.

incorporate a "wind-on" spool if specified in Clause D13.

### 20 Verification of Calibration of Instruments

Shall:

comply with HTM 2010 Validation and Verification.

# SMALL STEAM STERILIZERS FOR SURGICAL INSTRUMENTS

## SECTION C ELEMENT 03

### 21 Control Systems - General

Shall:

be supplied complete with all necessary power supplies, software, sensors and recording devices.

where the sterilizer has the capability to electronically transfer data direct to the manufacturer, provide a facility for the purchaser to review such data.

where electronic transfer facilities are included, provide a system where changes to the process performance of the sterilizer are prevented without the prior authorisation of the User.

only use software to control the machine that has been produced in accordance with a formal documented quality system and then subjected to a formal validation programme. Evidence of this shall be available if requested.

provide evidence that the complete programme and software for machines controlled by a micro-processor has been lodged with an independent body together with instructions. In the event of the tenderer ceasing to trade or failing to attend to software related problems, or defect/hazard investigation, the purchaser shall then have access to the programme and software. Details of this independent body shall be submitted with return of tender clause D19.

when a microprocessor is used to control or monitor the process, the supplier shall document the values of cycle variables critical to process performance and determined during validation, regardless of whether or not they are held in the microprocessor memory.

have the version number of the software used in the microprocessor clearly identifiable.

### 22 Microprocessor Systems

Shall:

be discrete for each sterilizer.

be completely separate from central processors controlling other operations such as a building energy management system.

include for all controls, transducers, indicators and instruments to function correctly in ambient conditions described in Clause C03.01 of this Specification. The Manufacturer to pay due attention to the location of controls and cycle start units and ensure that they are not sited where they will be affected by heat or moisture. The instrumentation and controls to be located clear of the area above the sterilizer door.

have the automatic control sequence initiated by a single action by the operator with only one single action start position on the sterilizer. Where a bar code or batch code entry system is provided the cycle to remain inactive until a valid code is entered.

# SMALL STEAM STERILIZERS FOR SURGICAL INSTRUMENTS

## SECTION C ELEMENT 03

include facilities to enable appropriate sensors, control items and stages of the process to be temporarily disabled during validation so that the applicable requirements of HTM 2010 Validation and Verification can be met.

at all times maintain safe conditions within the chamber and be arranged such that in the event of a failure it will not cause a safety hazard.

have means to ensure that the microprocessor sensor(s) and timing devices are functioning correctly and provide a fault indication when this is not so.

incorporate at least two timing systems independent of each other when combined control and monitoring systems that are wholly operated by means of a microprocessor are used.

be arranged for safety devices requiring power sources to be independent from the processor.

where the operating sequence of the unit is controlled by measurement of process values and where the attainment of such values may affect the safety of the machine or the effectiveness of the process, ensure that such measurements be determined from more than one sensor when independent monitoring (process verification) systems are not fitted.

where the measured values from such sensors differ by more than one preset level initiate a fault condition.

provide serial advance through a sequence of stages. The stage in process to be indicated on the front fascia panel.

have external connections from the processor unit to each hardware peripheral component (e.g. printer, disk drive etc) via a suitable identifiable connection plug and associated socket complete with identification to ensure correct connection.

except for items associated with sensors, provide for the programmable controller to contain all the components necessary for its function together with a watch dog system for the safe operation of the process. (See Part 2 of Programmable Electronic Systems in Safety Related Application, paragraph 199.)

have means to prevent damage to the microprocessor in the event of over-voltage being applied through the mains input connections. For external connections each input and output to include a means to check, at commencement of cycle, all peripherals and inputs and outputs are connected and not identifying faults. This may be a simple indicator (e.g. LED) or a more sophisticated alarm system built into the microprocessor.

if memory module/cards are used for programme storage (utilising non volatile memory) they should incorporate on to the circuit board a removable rechargeable battery with connections of the solderless type to be used. A change back-up battery status and an indicator to be provided showing state of charge. A warning is to be provided indicating when battery replacement is required. The battery backup should be positioned to allow easy access for changing batteries.

# SMALL STEAM STERILIZERS FOR SURGICAL INSTRUMENTS

## SECTION C ELEMENT 03

incorporate an operational mode feature allowing the Maintenance and Test Engineer to undertake the range of tests recommended in HTM 2010 and DB 98. Access to this feature to be by code or key.

have counter-measure against power failure such that should a power failure occur during a cycle the programme will, when power is restored, terminate the cycle in a safe condition, indicate a failed cycle, and the door interlocked to allow access by an authorised person only.

ensure that where the sensing element of any safety system involves an electrical switch, there be no other contacts or circuits of any sort in parallel with the switch whereby, either during normal operating or malfunction, power could by-pass the switch. Equivalent principles to produce the same effect to apply in the case of non-electric systems.

be capable of programmed operation by the use of firmware or software.

perform as designed when subjected to electromagnetic or electrostatic interference as specified in BS EN 60601-1-2.

### **23 Communication Port and Interfaces**

Shall:

be provided for the following:

- (a) input of signals for calibration tests;
- (b) output to an external data storage device such as a PC if specified in clause D13.

if specified in clause D17, comprise a machine mounted port and interface with the logic unit for an identification mark reader e.g. a bar code reader or RF device. The device to employ the specified coding system for identifying the types and quantities of the load items being processed and user ID for loading/unloading; transfer the interpreted identification mark characters in alpha-numeric codes to the printer and storage device (if specified); to give a hard copy of the codes which have been read when the sterilizer is loaded. The identification mark reader to be operable only when the sterilizer is being loaded.

### **24 Cycle Counter**

Shall:

be a tamper-proof or sealed counter with at least 5 digits to indicate the cumulative total of cycles started and be visible to the operator. This may be achieved by mechanical, electrical or digital device.

### **25 Maintenance Access**

Shall:

be such that all parts requiring servicing are easily accessible and be so designed that all panels are easily removable for maintenance purposes.

# SMALL STEAM STERILIZERS FOR SURGICAL INSTRUMENTS

## SECTION C ELEMENT 03

### 26 Electrical Supply, Wiring and Switchgear

Shall:

be via one electrical connection to the machine complete with all internal electrical wiring.

have earth connections on removable conductive panels (not reliant on a hinge or the panel screw).

be designed to operate with a single phase 13-amp electrical supply.

such that all individual switches on the outside surfaces of the sterilizer have an IP rating of 44 when tested in accordance with EN 60529 : 1991.

have the control/indicator panel designed to be resistant to the ingress of water, steam and/or condensate during normal operation of the machine.

have switches provided for start i.e. cycle commence and for cycle selection.

### 27 Ventilation

The sterilizer shall:

be designed to safely operate within an area that has no mechanical ventilation systems supplying it.

### 28 Water Reservoir

Shall:

incorporate a valve or other device to allow it and associated pipework to be drained by the operator or the automatic control system.

be large enough to contain sufficient water for:

a) the running of a complete sterilization cycle;

**or**

b) the number of consecutive operating cycles specified by the manufacturer. The cycle specified should be for the test load having the maximum steam consumption.

be provided with a means to indicate whether the water quantity in the reservoir is sufficient for an operating cycle.

be linked to prevent the sterilizer from starting a cycle if there is insufficient water in the reservoir.

be vented and its design shall facilitate cleaning, inspection and filling.

include for all water services and associated equipment to comply in all respects with the Water Supply (Water Fittings) Regulations 1999.

# SMALL STEAM STERILIZERS FOR SURGICAL INSTRUMENTS

## SECTION C ELEMENT 03

### 29 Water Quality

Shall:

be designed for use with water of a quality not less than that suitable to produce steam in accordance with HTM 2031.

**Note:**

Specification for clean steam as defined by HTM 2031

| <b>Determinant</b>                                  | <b>Value</b>               | <b>Recommended test for compliance</b>                                  |
|---|----------------------------|---|
| <i>Based on Sterilized Water for Injections BP:</i> |                            |   |
| Acidity or alkalinity.                              | NQ                         | BP test. Tests for pH are not an acceptable substitute                  |
| Ammonium  | 0.2 mg litre <sup>-1</sup> | BP test or other suitable method  |
| Oxidisable substances.                              | NQ                         | BP test   |
| Calcium and magnesium                               | NQ                         | BP test. Tests for hardness are not an acceptable substitute.           |
| Heavy metals.                                       | 0.1 mg litre <sup>-1</sup> | BP test. Tests for individual elements are not an acceptable substitute |
| Chloride  | 0.5 mg litre <sup>-1</sup> | BP test or other suitable method.                                       |
| Nitrate   | 0.2 mg litre <sup>-1</sup> | BP test or other suitable method.                                       |
| Sulphate.   | NQ                         | BP test   |
| Residue on evaporation                              | 30 mg litre <sup>-1</sup>  | BP test. Conductivity measurement is not an acceptable substitute.      |
| Pyrogens  | 0.25 EU ml <sup>-1</sup>   | BP test.  |
| <i>Based on EN 285:</i>                             |                            |   |
| Phosphate   | 0.1 mg litre <sup>-1</sup> | Any suitable method.  |
| Silicate.   | 0.1 mg litre <sup>-1</sup> | Any suitable method   |
| <i>Routine monitoring only:</i>                     |                            |   |
| Electrical conductivity at 25°C                     | 35 µS cm <sup>-1</sup>     | See HTM 2031, Appendix 4 and Chapter 7                                  |

NQ = not quantified; BP = British Pharmacopoeia; EU = endotoxin unit

(Consideration should be given to single shot type sterilizers, where water is not returned to the reservoir at the end of the cycle).

### 30 Noise Emission & Sound Power

Shall:

comply with HTM 2010 Part 3.

# SMALL STEAM STERILIZERS FOR SURGICAL INSTRUMENTS

## SECTION C ELEMENT 03

The Tenderer shall:

using the procedure described in clause 8.1 of BS EN ISO 3746 whilst the sterilizer(s) are operating, determine the following;

- a) the daily personal noise exposure (LEP'd);
- b) the peak sound pressure level.

the test should be considered satisfactory, if the following requirements are met:

- a) the daily personal noise exposure does not exceed 55dB(A);
- b) the peak A-weighted sound pressure does not exceed the daily personal noise exposure.

carry out any modifications to the sterilizers resulting from the failure of the above assessment.

accept responsibility and carry out any modifications to the small washer-disinfector(s) resulting from the failure of the above assessment.

### **31 Thermal Emission, Surface Temperatures and Insulation**

Shall:

ensure that no surface exceeding 55°C is exposed to the room when the machine is closed and working under its normal operating conditions.

consist of materials which are non-flammable and heat resistant which, when applied, allow for any access to all components for maintenance purposes. Sectional glass silk, asbestos and asbestos-containing products are excluded for these purposes.

### **32 Hydrostatic Test**

Shall:

be carried out at the manufacturer's works and a certificate certifying satisfactory completion of the hydrostatic test specified in PD 5500:2003, signed by a responsible employee of the manufacturer, or insurance company, forwarded to the Engineer at the time of delivery or, where a vessel is not covered by PD 5500:2003, be certified by an independent examiner to have been successfully carried out.

# SMALL STEAM STERILIZERS FOR SURGICAL INSTRUMENTS

## SECTION C ELEMENT 03

### 33 Operating Instructions

Shall:

be provided and fixed to the machine and comprise a permanently marked notice giving clear and simple operating instructions and stating the classes of articles which can be processed in each individual cycle of the machine e.g. for Type B machines “wrapped goods and porous load”, for Type S machines “Lumened devices” and for Type N machines “unwrapped bowls and instruments” etc as appropriate.

### 34 Delivery and Packing

The Tenderer shall:

include for delivering the sterilizer to site and off-loading from the delivery vehicle and moving it to the specified location, as defined in Clause D01, appropriately packed to prevent accidental damage.

### 35 Technical Documents, Manuals, and Other Documentation

Shall:

be supplied upon delivery of the sterilizers and comprise a complete set or a number specified in Clause D06 of technical literature on the operation, maintenance and validation of the sterilizer, together with a copy of record drawings showing the pipework and electrical circuitry of the machine.

include spare charts, printer rolls, pens and printer ribbons as specified in Clause D08.

include a complete planned preventive maintenance programme showing the tasks to be carried out at regular intervals, including the replacement intervals for critical parts and consumables, compatible with the standard planned preventive maintenance intervals which may include:

- (a) weekly;
- (b) monthly;
- (c) quarterly;
- (d) half yearly;
- (e) yearly;
- (f) two yearly.

if requested in clause D06 include for the supply of an operational chart showing the detailed sequence of events and operating parameters during a normal cycle and indicate what will happen at each stage or sub-stage of the cycle if the parameter controlling that stage or sub-stage, e.g. chamber pressure, temperature etc is not satisfied. For microprocessor-controlled machines the following programming features and menus to be provided:

- (a) Door operation and cycle, start procedures;
- (b) Door operation at the end of a cycle;
- (c) Aborting a cycle;
- (d) User's menu;
- (e) Maintenance engineer's menu with optional mimic diagram;

# SMALL STEAM STERILIZERS FOR SURGICAL INSTRUMENTS

## SECTION C ELEMENT 03

- (f) Operating security levels;
- (g) Address lists, and values of process variables;
- (h) Calibration of instruments;
- (i) Interrogation of registers holding process variables;
- (j) Input and output status at all stages;
- (k) Diagrams to show the status of all inputs and outputs for each stage of the process.

list typical causes of failure during a faulty cycle and their remedy.

include copies of all relevant certification including calibration certificates for all instruments fitted to the sterilizer.

### **36 Training**

Shall:

include information regarding the safety features fitted to the sterilizer.

be provided by the Tenderer as defined in clause D16.

take account of the mixed ability and capabilities of the personnel defined in Clause D16 and be provided by the demonstrators/lecturers with substantial experience of the machines to be demonstrated, the time required to provide this instruction to be stated in clause D30 at the time of tender.

provide a certificate of training for staff who have completed the training to operate and/or maintain the sterilizers correctly.

during the warranty period, be provided as detailed in the clauses above in respect of any upgrade or modification carried out by the manufacturer that requires a change in either maintenance or operational policy.

when requested in clause D16, detailed costings of further advanced training options will be identified in D29.

### **37 Installation, Operational and Performance Qualification Testing**

Shall:

take place after installation of the sterilizer and include for fully commissioning the machine in accordance with HTM 2010 and if specified in clause D10 undertake further operational and performance qualification tests.

be witnessed by a representative of the Purchaser (e.g. Authorised Person (Sterilizers)) as specified in Clause D10. Where a purchaser representative has been nominated all validation documentation shall be available for audit prior to acceptance of the machine(s) by such persons.

# SMALL STEAM STERILIZERS FOR SURGICAL INSTRUMENTS

## SECTION C ELEMENT 03

be arranged by the supplier with at least 14 days clear notice to be given of the planned date of test. Any expenditure involved as a consequence of the supplier cancelling the arranged date for witnessing the tests will be met by the supplier.

be undertaken with any device or equipment required for the purpose of conducting the commissioning/routine tests being provided by the manufacturer.

be undertaken using test loads supplied by the tenderer if specified in clause D12. Any additional costs involved for the provision of such equipment shall be clearly identified prior to contracting to provide the machine.

be undertaken using only test equipment calibrated as recommended in HTM 2010 and that calibration traceable to national standards.

result in the issue of validation documentation including the original copies of all installation and validation test results within one month of completion of the validation process.

### **38 Servicing and Maintenance**

The tenderer shall:

include within the priced schedule, the cost for the first 12 month's maintenance of the sterilizer.

specify the service time required to carry out all routine maintenance tasks and for the replacement of all major components.

undertake service visits in accordance with the recommended planned maintenance schedule. The number of visits included during the warranty period shall be documented in the return tender in clause D20.

submit a comprehensive, written, service report in respect of each service visit, giving full details of the work carried out including validation test data where appropriate.

not change during servicing, operational values of any of the variables established during performance testing as critical to successful processing, without the prior written consent of the purchaser.

on completion of the appropriate service, if required in D10, carry out the periodic testing specified in HTM 2010 to verify that the performance criteria established during commissioning remain valid.

in the event of a breakdown and at the request of the purchaser, provide a service engineer on site within the response time requested by the purchaser as specified in clause D11.

be able to provide all replaceable components, for use in the event of breakdown, for a period of not less than 7 years from the date of installation. These shall be charged for only as and when they have been supplied and fitted.

# SMALL STEAM STERILIZERS FOR SURGICAL INSTRUMENTS

## SECTION C ELEMENT 03

provide a list of recommended service spares and consumable items for one year's use to be included and priced in Section D22. The spare parts list shall be comprehensive with clear identification of those items held in stock (i.e. available on site the next day by courier delivery if required see above). The lead times required for delivery of non-stock items shall be specified. Details of the quantity and frequency with which each consumable item is required shall be included.

### **39 Additional Information to be supplied by the Tenderer**

#### **Prior to contract**

The tenderer shall:

state the conditions necessary to meet the performance requirements for each stage of the process and for each operating cycle. For each operating cycle that can be used the following parameters shall be described by the manufacturer:

- a) any restrictions on use, in particular, the type of products which the programme is designed to sterilize; this information shall be based on validation studies on specific products or product families;
- b) the accessories that shall be used;
- c) the physical parameters of the processes e.g. time, temperature, vacuum.

**End of Element**

## SECTION C ELEMENT 04

### TEST METHODS

04

**Note:**

The tests described within element 04 of this document are only those deemed adequate to establish the particular requirements of clause 03.07. They do not constitute the full range of tests required for installation, operational or performance qualification of a new sterilizer. HTM 2010 and the advice of an Authorised Person (Sterilizers) should be consulted in order to establish the extent of testing required.

#### 01 General

Testing shall be carried out in accordance with HTM 2010 using specified test loads, except as modified within this specification.

From the time when testing commences on site all test runs, whether successful or not, shall be recorded and documented.

The cycle data from the controller (where practicable) and from the process recorder shall be retained as part of the record of each cycle.

The test report shall include a summary sheet identifying all test cycles run.

The instruments used to test the sterilizer and those used to calibrate the test instruments shall be calibrated to the standards required in HTM 2010.

#### 02 Sterilization

The attainment of thermal sterilization shall be determined by the measurement of the temperature attained on the surfaces to be sterilized. More than one time temperature relationship may be required to be qualified.

The attainment of sterilization conditions shall be demonstrated on three consecutive cycles for each of the load types to be processed.

#### 03 Microprocessor Controller - Acceptance Test Procedure

Shall:

in addition to tests described for the general commissioning of the sterilizer be possible to demonstrate to the satisfaction of the purchaser's representative:

- (a) During an automatic cycle it is not possible to change to another automatic cycle and the safety features of the cycle first selected cannot be circumvented;
- (b) After power failure there is no memory loss of software programme and calibration data;
- (c) On power failure safety features of the cycle cannot be circumvented;
- (d) Power supply restoration, check upon the performance as detailed above;
- (e) Battery "change" condition (where the programme is stored in the battery backed memory);
- (f) Means to easily change battery without loss of programme;
- (g) Operation of safety systems;

## SECTION C ELEMENT 04

- (h) Sensor failure checks;
- (i) Be possible to validate the process cycle;
- (j) Be possible to validate the instrument calibration;
- (k) Printer self check print.
- (l) For process value measurement, cause an alarm when differential exceeds tolerance limit.

**End of Element**

## SECTION D

### BENCHTOP STERILIZERS

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**End Index D15**

## SECTION D

**Scope (Ref C02.01, C03.14, C03.34, C03.39)**

**01**

This section shall:

be read in conjunction with Part C.

be completed, where required, by the Purchaser and where indicated, by the Tenderer.

be returned by the Tenderer duly completed to the Purchaser as part of the tender documents.

Please complete subclause D01a for detailing specific machine requirements.

**Surgical specialities catered for:**

| <b>Types of Instrument</b>                              | <b>Packaging System</b>                          | <b>Comments (e.g. maximum dimensions, number of lumens)</b> |
|---|--|---|
| Solid Loads<br>(Probes, Tweezers Solid Instruments etc) | Protection during normal shipping/transportation | To be specified by GDP                                      |
| Small Porous<br>(Guaze, CoHon etc)                      |  |   |
| Hollow Loads (pouch)                                    |  |   |
| a.      Wrapped hand pieces,<br>forceps, scissors etc   |  |   |
| b.      Tips, simple hollow items                       |  |   |

## SECTION D

Delivery requirements for sterilizer(s) it is the responsibility of the supplier to establish and allow for the access/delivery requirements of equipment proposed within this tender.

\*DELETE AS NECESSARY

### Specific Machine Requirement

**01a**

The sterilizers covered by this section are (sterilizers to be included within the tender):

| <b>M/C ID</b> | <b>Type</b> | <b>Cycles required</b>   | <b>Chamber Size/Dimensions</b>                             | <b>Location</b>      |
|---------------|-------------|--|--|----------------------|
| A             | “B”         | 1. Standard Porous Load<br>2. Extended Porous Load<br>3. Test Cycles<br>A. Bowie Dick/Helix<br>B. Vacuum Leak Test<br>C. Air Detector Function Test<br>D. Air Detector Performance Tests | Approximate: 17 or 22 Litre 250mm diameter 450/550mm depth | Decontamination Room |
| B             | “N”         | Non Wrapped Solid Items (Additional Feature, 134 <sup>0</sup> C with Drying)   | Approximate: 17 or 22 Litre 250mm Diameter 450/550mm Depth | Decontamination Room |

**SECTION D**

**Personnel Nominations**

**02**

**Nominations:**

**Contact Telephone No.**

Purchaser: AN other Dental Practice .....

Test Person (Sterilizers): To be nominated by Supplier .....

User: (Person designated responsible for the Management of the Sterilizers .....

Primary Contact: Complete if required .....

**Terms and Condition of Supply Contract**

**03**

This may be based on the specific supplier terms and conditions of contract.

**Site Access**

**04**

Site Details: The sterilizer being purchased is to be installed in a GD Practice., Decontamination room. It is the responsibility of the supplier to allow and agree the access requirements for the equipment proposed in this tender.

Expected date when ready for delivery To be agreed

**Schedule of Drawings Included with Specification**

**05**

| <u>Drawing Number</u> | <u>Title</u>   |
|-----------------------|--|
|                       | Building alternations and equipment layout drawings to be provided by Project Team, if any |

## SECTION D

### Documentation and Record Drawings Required at Installation (Ref C03.35)

**06**

| <u>Number Required</u>  | <u>Description</u>   |
|-------------------------|--|
| Provide 1 set of each:- | Pressure systems written scheme of examination for the sterilizer, factory thermocouple type tests, calibration certificates for all instruments, traceable to National Standards or UKAS certified. |

### Removal and Disposal of Existing Equipment

**07**

Details: GDP to List Decontamination Equipment to be removed and disposed of.

If required, the contractor/supplier of new equipment shall be responsible for:-

- (a) Disconnection and removal of redundant sterilizers.
- (b) Disposal of equipment to be, as recommended by the manufacturer and restrictions laid down under the respective Town/City Council waste/disposal management guidance.

### Particular Machine Details

**08**

Chamber material.

Stainless Steel.....

Door requirements

\*~~Single/Double ended~~

\* DELETE AS NECESSARY

Details of spare charts, printer rolls, printer ribbons etc, requested.

**\*YES/NO**

Sufficient items to be provided to last through Validation/Commissioning Tests and 6 months after validation (based on 4 cycle per day).

Position of recorder printer sensor.

As per manufacturer's Designed Location

Needle valves and non-return valves required for:

**\*YES /NO**

Type 'B' Sterilizer only

**SECTION D**

**Requirements for Special Loads** **09**

Details: Comprehensive range of accessories to facilitate the various load Types/Loading Patterns described in section D15-01 shall be supplied for Type ‘N’ and B’ sterilizers

**Testing (Ref. C03.37, C03.38)** **10**

1. Installation testing (as per HTM 2010) to be performed by: Supplier nominated TP(S)
2. Operational testing (as per HTM 2010) to be performed by: Supplier nominated TP(S)

Details of deviations from HTM 2010 Validation and Verification for Installation and Operational Testing: (Compliance with DB(NI) 2002/06 Benchtop Steam Sterilizers – Guidance on Purchase, Operation & Maintenance + DB(NI) 9901 The Validation and Periodic testing of Benchtop Vacuum Steam Sterilizers.

3. Performance Qualification tests (as per HTM 2010) to be performed by supplier nominated TP(S) for the load types detailed below:

Details of PQ Tests Required:

Comprehensive range of load items specific to the GDP procedures shall be tested out for each Sterilizer Type ie “N” and “B”.

4. Inspection/Audit: ..... Randomly ..... **YES**

This specification includes for this requirement for periodic testing of the equipment and Dental Practices will be expected to have recorded evidence available for inspection/audit of the required periodic tests as stipulated. As a minimum, evidence of an annual validation will be expected.

Addition maintenance requirements

Details: To be in accordance with manufacturer’s instructions and DB(NI) 2002/06/DB(NI)9901

.....

**Service response (Ref C03.38)** **11**

Required service response time (for engineer to arrive at site): Within 24 hours of reported fault. Repair to be completed within 48 hours of notification of fault (Monday to Friday) 5 days per week. The supplier/contractor shall have adequate resources to ensure compliance to above.

**SECTION D**

**Test Equipment, Test Loads & Materials to be Provided within the Tender for Testing on Site and handed over to the Purchaser on Completion of Testing (Ref. C03.37) 12**

**For example: Test packs and process challenge devices**

| Number        | Details  |
|---------------|--|
| As required:- | Type 'B' Sterilizers<br>Bowie Dick single use Daily Test Pack or manufacturers Helix test kit – conforming to EN867-5 Chemical and Test Loads for small sterilizers, DB(NI) 2002/06 and recommendations of MHRA. |

Daily test packs/consumables required

Details: Sufficient items shall be provided to last through commissioning tests and 6 months after validation.

**Machine Chart Recorder/Printer (Ref. C03.17, C03.19) 13**

Printer Required? **\*YES/NO**

Data source? \*Controller/~~Independent~~/~~Both~~

Location of printer: \*Integral/~~Adjacent~~/~~Other~~  
Loading side

Details of Print format:

- (a) Time, date, cycle type and operator identification
- (b) Process data: time, temperature, pressure and Pass/Fail all as C03/17.

“Operator identification” format.....  
Space required on print-out for handwritten notes? E.g. load details **\*YES/NO**

## SECTION D

Printer Process Data Parameter Units - Process: temperature ( $^{\circ}\text{C}$ ) Pressure (Pa) or (mbar)

Archive data storage device required \*YES/NO

Location of archive data storage device: To be agreed with designated User

### Process Variable Monitoring (Ref. C03.17)

14

**Note:**

The default process variables that require monitoring are listed within C03.17 of this specification and vary depending on the type of sterilizer being specified. The option here allows the specifier to choose the default variables from the particular relevant section by deleting those sections not relevant, or to individually specify each variable.

Process monitoring required \*Independent/Watchdog

For independent monitoring:

Air detector temperature/pressure (depending on system used) \*YES/NO

Chamber reference temperature \*YES/NO

Chamber temperature \*YES/NO

Chamber pressure \*YES/NO

Details of Additional Monitoring/Instrumentation Required:

.....None.....

**SECTION D**

Electronic storage of independent data required \*~~YES~~/~~NO~~

- Details:
1. Supplier shall submit details of proposed electronic storage in this Tender document.
  2. To allow periodic transfer of data (by manufacturers preferred method) from Sterilizer to PC or net work server.

.....  
\*DELETE AS NECESSARY

**Delivery Packing Method (Ref C03.34) 15**

\* Standard Packaging.....~~YES~~/~~NO~~

\* In weatherproof packing: YES if subjected to wet conditions

Other Details: N/A

\* DELETE AS NECESSARY

**Staff Training Required (Ref C03.36) 16**

Number of User Staff to be trained: 4

Number of Other Staff to be trained (please specify) 0

Details of room and training aids to be made available by Purchaser: If required all aids shall be provided by the Supplier However operating training shall be within the room in which the sterilizer is located.

Items to be included (delete where inapplicable):

**Introduction-** An explanation of the purpose of the sterilizer and the cycles.

**User Instructions** - An introduction to the sterilizer, loading the sterilizer, starting a cycle, unloading, routine tasks e.g. cleaning seals, replacing record charts, printer paper rolls, computer downloading, archiving and retrieving information.

Maintenance shall be the responsibility of the supplier under contract.

**SECTION D15**

**Automatic Control Test** - A weekly automatic control test plus leak test (if fitted) shall be demonstrated, with students completing the record sheets which will be used at the hospital.

Advanced training options and costing required **\*YES / NO**

Details:

**Details of Microprocessor Controller(s)** (Ref C03.23) **17**

Traceability interface and reader port required (e.g. bar-code system) **\*YES/NO To be supplied as an option**

Traceability reader required (e.g. bar-code reader) Number Required 2.....

Reader format details (e.g. barcode, dot matrix etc.) To be specified by supplier dependant on suppliers preferred options.

\*DELETE AS NECESSARY

**Available Services** **18**

**Details:** 2. Tenderer's shall note all sterilizer(s) supplied under this Contract shall be capable of processing the specified items generating steam from water via an Reverse osmosis water plant. (For further details regarding RO Water Plant please contact Designated User or Health Estates AP(s)).

Please note the RO water plant is specified in MES Specification for Small Washer Disinfectors which is in conjunction with the overall General Dental Practice procurement exercise.

Cost of utilities (to be supplied for calculation purposes)

|             |                      |   |       |
|-------------|----------------------|---|-------|
| Water       | ) to be supplied     | £ | /ltr  |
| Electricity | ) by GDP on request  |   | p/kWh |
| Other:      | <u>Not Available</u> |   |       |

**SECTION D**

**INFORMATION TO BE COMPLETED BY TENDERER**

**Details of Microprocessor Control System (Ref. C03.21, C03.22) 19**  
**The following information shall be provided by the Tenderer.**

Details of independent body where complete programme and software are lodged.

Maximum ambient temperature within the protective case .....°C  
with an ambient temperature of .....°C

**Warranty Details (Ref. C03.38) 20**

Length of standard/free warranty period offered:

Number of included service visits during warranty period:

**Conditions of warranty: 21**

Projected mean time between failures:

Guaranteed up-time:

Please state definition of up-time

.....  
.....  
.....  
.....

Please state remedy available to purchaser if guaranteed up-time is not achieved

.....  
.....  
.....

Expected life of vacuum pump (if fitted)

.....

**SECTION D**

**Extended warranty options for service and maintenance:** (Ref. C03.38)

**22**

Please complete the following schedule with regard to a planned preventative maintenance and emergency call out contract to cover all items shown in the individual site schedule and to commence after the completion of the tenderer's warranty period if required by the purchaser:

Number of service visits ..... per annum

Duration of service visits.....hours per machine

Normal working hours are 0830-1730, unless otherwise stated:

All emergency call-outs included YES/NO

Price for emergency call-out during normal working hours,  
if not included £..... per hour

All out of hours working included YES/NO

Price for Saturday working £.....per hour

Price for Sunday working £.....per hour

Price for evening working £.....per hour

Price for bank holiday working £.....per hour

Response time to emergency call-outs (engineer on site) ..... hours

Latest time on a working day to guarantee engineer on site same day .....

Base of engineer to service this site .....

How many other sites does he/she service .....

Number of engineers available to service this site .....

All spare parts included **\*YES /~~NO~~**

Please list any parts that are not included that appear on the following lists :

**SECTION D**

Five most used commodities by volume

| Description | Part No | Delivery lead time | Price (exc VAT) |
|-------------|---------|--------------------|-----------------|
| 1.....      |         |                    |                 |
| 2.....      |         |                    |                 |
| 3.....      |         |                    |                 |
| 4.....      |         |                    |                 |
| 5.....      |         |                    |                 |

Five most used commodities by value:

| Description | Part No | Delivery lead time | Price(exc VAT) |
|-------------|---------|--------------------|----------------|
| 1.....      |         |                    |                |
| 2.....      |         |                    |                |
| 3.....      |         |                    |                |
| 4.....      |         |                    |                |
| 5.....      |         |                    |                |

Delivery lead time for spare parts .....

Comments:

Is Remote Maintenance and Diagnosis via modem available:     \*~~YES~~/ NO

Price for supply and installation:                     £.....

Software Upgrades (during warranty or maintenance contract period):

Safety / Defect Upgrades                                 \*Free of charge / At cost

New Applications   \*Free of charge / At cost

Annual maintenance contract costs including validation to HTM 2010:

Total Contract price for one year                     £..... exc VAT

Five year maintenance contract                     Year 1     £..... exc VAT

|   |        |                |
|---|--------|----------------|
| (fixed to retail price index)   | Year 2 | £..... exc VAT |
|   | Year 3 | £..... exc VAT |
|   | Year 4 | £..... exc VAT |
|   | Year 5 | £..... exc VAT |
| Quarterly Periodic<br>Validation Costs<br>(fixed to retail price index) | Year 1 | £..... exc VAT |
|   | Year 2 | £..... exc VAT |
|   | Year 3 | £..... exc VAT |
|   | Year 4 | £..... exc VAT |
|   | Year 5 | £..... exc VAT |
| Annual Validation Costs<br>(fixed to retail price index)                | Year 1 | £..... exc VAT |
|   | Year 2 | £..... exc VAT |
|   | Year 3 | £..... exc VAT |
|   | Year 4 | £..... exc VAT |
|   | Year 5 | £..... exc VAT |
| Contract price for one year   |        | £..... exc VAT |

The maintenance contract will be at this price plus price increases in accordance with the retail price index. These costs are not to form part of the total costs detailed in clause D35 but are to be provided as an option.

\* DELETE AS NECESSARY

**Service Requirements** (Ref. C03.13)

**23**

**The following information shall be provided by the Tenderer for each type of machine supplied. (Based on an full load as identified in D18)**

| SERVICE   | REQUIREMENTS |
|---|--------------|
| machine number                                      | .....        |
| water consumption per cycle                         | .....        |
| electricity current                                 | .....        |
| electricity maximum power kW                        | .....        |
| air filter (air removal) expected life              | .....        |
| sound power   | .....        |
| Usable chamber volume                               | .....        |
| dimensions of maximum load accommodated (L x W x H) | .....        |

**SECTION D**

total energy cost per cycle (please specify cycle type, based on load detailed and using figures supplied in clause D18)

.....

**Overall Cycle(s) Time(s)**

**24**

The following information shall be provided by the Tenderer.

| <b>Load</b> | <b>Performance Class Type</b> | <b>Anticipated Cycle Time</b> |
|-------------|-------------------------------|-------------------------------|
|             |                               |                               |

**Overall Sterilizer Dimensions**

**25**

The following information shall be provided by the Tenderer.

| <b>m/c no</b> | <b>max floor/bench area</b> |          | <b>height</b> | <b>mass</b> | <b>max floor/bench loading (full load) mass</b> | <b>max fascia opening</b> |          |          |
|---------------|-----------------------------|----------|---------------|-------------|---|---------------------------|----------|----------|
|               | <b>l</b>                    | <b>w</b> | <b>h</b>      | <b>kg</b>   |   | <b>kg</b>                 | <b>w</b> | <b>h</b> |
|               |                             |          |               |             |   |                           |          |          |

**Porterage Details**

**26**

The following information shall be provided by the Tenderer.

Details (including weight of packing materials and dimensions):

**SECTION D**

**Heat Emission**

**27**

**The following information shall be provided by the Tenderer.**

Heat emission during normal operation at ambient temperature of 25°C:-

To installed room - with sterilizer door closed ..... W

**Contract Completion**

**28**

**The following information shall be provided by the Tenderer.**

delivery time from receipt of order ..... weeks

time required for installation and  
pre-commissioning on site ..... weeks

time required for commissioning on site ..... weeks

**SECTION D**

**Detailed Cost Breakdown:**

29

**The following information shall be provided by the Tenderer.**

| Item Type   | Model Name/No | No. of | List Price per Unit | Discount % | Actual price per Unit | Total Price |
|---|---------------|--------|---------------------|------------|-----------------------|-------------|
| Sterilizer a  |               |        |                     |            |                       |             |
| Sterilizer b  |               |        |                     |            |                       |             |
| Sterilizer c  |               |        |                     |            |                       |             |
| Sterilizer d  |               |        |                     |            |                       |             |
| Chamber Furniture a                                   |               |        |                     |            |                       |             |
| Chamber Furniture b                                   |               |        |                     |            |                       |             |
| Chamber Furniture c                                   |               |        |                     |            |                       |             |
| Controls  |               |        |                     |            |                       |             |
| Training  |               |        |                     |            |                       |             |
| Steam penetration test packs<br>(e.g. Bowie and Dick) |               |        |                     |            |                       |             |
| Additional Options                                    |               |        |                     |            |                       |             |

|  |
|--|
| List Items from table in D01 that cannot be processed within this sterilizer |
|  |

**SECTION D**

**Summary of Tender**

**30**

**The following information shall be provided by the Tenderer.**

**£**

|  |               |       |
|--|---------------|-------|
| supply ..... sterilizer(s)                         | 1 No Type "B" | ..... |
|  | 1 No Type "N" | ..... |
| supply monitoring recording and IMS Systems        |               | ..... |
| delivery & offloading ..... sterilizer(s)          |               | ..... |
| site commissioning                                 |               | ..... |
| installation checks and tests                      |               | ..... |
| test equipment, test loads and materials           |               | ..... |
| 12 months service including 4 off quarterly visits |               | ..... |
| Quarterly Periodic Validation (5 year period)      |               | ..... |
| Annual Validation Costs (5 year period)            |               | ..... |
| staff training, consisting of ..... days           |               | ..... |
| supply chamber furniture type .....                |               | ..... |
| supply chamber furniture type .....                |               | ..... |
| supply ..... set(s) of recommended service spares  |               | ..... |
| SUB-TOTAL  |               | ..... |

..... VAT @ ..... % .....

**TOTAL**

.....

Signature: .....

Company  
(2<sup>nd</sup> signature) :.....

Position: .....

Address:.....

Company: .....

.....

Date: .....

Date: .....

**End of Section D**

**End of Specification**

# **ANNEX A: GUIDANCE ON COMPLETION OF SECTION D**

## **General**

Examples are provided in each section to assist GDPs in completion of the specification and the following notes give further information concerning specific sections.

## **Specification Reference: D-01**

### **SURGICAL SPECIALITIES CATERED FOR:**

#### **TYPES OF INSTRUMENT -**

We have listed the standard types of instruments normally used in GDP, however if you have additional/other instruments not on this list, these should be listed in this section.

#### **PACKAGING SYSTEM -**

Normal Packaging Protection has been specified however if additional Protection is required ie to suit special storage requirements such as building refurbishment, etc please specify in this section.

#### **COMMENTS - (eg Maximum Dimensions, Number of Lumens)**

Additional comments for any special requirements, specific instruments or load types can be listed under this section.

#### **DELIVERY REQUIREMENTS FOR STERILIZERS -**

We have stated it is the responsibility of the supplier to arrange access/delivery, if this is not acceptable or special arrangements are necessary – please state any information in this section.

## **Specification Reference: D– 01A**

### **SPECIAL MACHINE REQUIREMENT:**

#### **TYPE:**

We have stated two particular types of bench top sterilizers “N” and “B” Type. The GDP should refer to the accompanying guidance for selecting the most appropriate type of sterilizer although the B type is increasingly being specified for Dental Practice.

- N - Unwrapped Instrument & Utensil
- B - Porous Load vacuum

#### **CYCLES REQUIRED -**

B Type - Active air removal, wrapped or non-wrapped solid, hollow items and fabrics.

N Type - Passive displacement, non-wrapped solid items.

#### **CHAMBER SIZE/DIMENSIONS -**

We have specified two chamber sizes 17 litre (250mm Dia x 450mm depth) and 22 litre (250mm Dia x 550mm depth). If as a result of processing longer instruments/items requiring a longer chamber depth, please specify largest instrument dimensions in this section in order that the supplier can propose an

alternative chamber size.

**LOCATION -**

We have assumed the area/location in which the decontamination of instruments will take place shall be named the “Decontamination room”, however if this is not the case please state preferred location and room name.

**Specification Reference: D– 02**

**PERSONNEL NOMINATIONS:**

**PURCHASER**            Name of Dental Practice and telephone number to be inserted.

**USER**                    Name and telephone number of “Designated User” ie person responsible for the management of the Decontamination equipment.

**TEST PERSON (STERILIZERS)** - Name and telephone number of contracted nominated Test Person (Sterilizers).

**PRIMARY CONTRACT** - Name and telephone number of primary contact to be inserted (if nominated).

**Specification Reference: D– 03**

**SELECTION OF TERMS AND CONDITIONS:**

Standard Terms and Conditions of Contract shall apply and be agreed between supplier and purchaser.

**Specification Reference: D– 04**

**SITE ACCESS/SITE DETAILS:**

We have assumed NO site access difficulties exist however if access/delivery problems are envisaged please state them within this section.

**Specification Reference: D– 05**

**SCHEDULE OF DRAWINGS:**

We have assumed NO drawings/room layouts are to be included however if such documents/information are available they should be listed within this table.

## **Specification Reference: D– 06**

### **DOCUMENT AND RECORD DRAWINGS REQUIRED AT INSTALLATION:**

We have assumed no “as installed” drawings shall be available however if they exist they should be listed in this section.

### **DOCUMENTATION -**

We have listed several documents in relation to Health & Safety legislation and acceptable factory type tests. These should be made available before validation/commissioning tests commences.

## **Specification Reference: D– 07**

### **REMOVAL AND DISPOSAL OF EXISTING EQUIPMENT:**

We have assumed no existing decontamination equipment shall be removed and disposed of, however if equipment is replaced and made redundant, information should be inserted in this section.

## **Specification Reference: D– 08**

### **PARTICULAR MACHINE DETAILS:**

#### **CHAMBER MATERIAL/DOOR REQUIREMENTS -**

We have specified, manufacturers standard stainless steel construction and front single door operation.

#### **SPARE CHARTS, PRINTER ROLLS, PRINTER RIBBONS -**

We have specified sufficient items to be provided to last through commissioning tests and 6 months after validations (based on 4 cycles/day). If this is not acceptable, specific requirements should be stated in this section.

#### **POSITION OF RECORDER/PRINTER SENSOR -**

The positions of the sterilizer process sensor shall be as per the manufacturers design.

#### **NEEDED VALVES AND NON RETURN VALVES -**

We have specified all components/values required to validate each specific sterilizer type shall be included by the supplier of the sterilizers.

## **Specification Reference: D– 09**

### **REQUIREMENTS FOR SPECIAL LOADS:**

We have specified it is the responsibility of the supplier to provide all load types necessary to comprehensively validate each sterilizer type as described in D15-01. If circumstances exist around availability to acquire such load items it may be necessary for the GDP to supply test loads. If this is envisaged as a problem a statement should be inserted in this section.

## **Specification Reference: D– 10**

**TESTING:****Installation/Operational Testing -**

We have specified all validation tests shall be carried out by a competent, qualified Test Person (Sterilizers) nominated by the supplier.

All tests shall be in accordance with the relevant HTM's and Device Bulletins.

**Performance Qualification Testing -**

We have specified PQ tests shall be performed by a competent, qualified Test Person (Sterilizers) nominated by the supplier.

It is the responsibility of the supplier/TP(s) to perform a comprehensive range of tests representative of the production loads processed in each sterilizer type.

**INSPECTION/AUDIT:** Health Estates has been working with local suppliers of decontamination equipment with the intention of building capacity in the local market for the provision of a suitably qualified testing service as part of the procurement and ongoing operational requirements of the equipment. The intention is that equipment will be supplied with a testing service offered as part of the package. This specification includes for this requirement for periodic testing of the equipment and Dental Practices will be expected to have recorded evidence available for inspection/audit of the required periodic tests as stipulated. As a minimum, evidence of an annual validation will be expected.

**Additional Maintenance Requirements -**

We have specified maintenance procedures shall be in accordance with the manufacturers instructions, however if additional functions are required these should be listed in this section.

**Specification Reference: D- 11****SERVICE RESPONSE:**

We have specified a service response time of 24 hours, of a reported fault/ breakdown – Monday to Friday. If however this is not acceptable or weekend call out response is required, this information should be inserted in this section.

**Specification Reference: D- 12****TEST EQUIPMENT, LOADS AND MATERIALS TO BE PROVIDED:**

We have specified several process challenge devices required for each sterilizer type. These devices assist in performing the recommended periodic testing, function protocols in order to check equipment performance against specified validated data.

**DAILY TEST PACKS/CONSUMABLES -**

We have specified sufficient number of daily test packs/consumables shall be provided to last through commissioning tests and 6 months after validation (based on 4 cycles/day).

If however this is not acceptable specific requirements should be stated in this section.

## **Specification Reference: D– 13**

### **MACHINE CHART RECORDER/PRINTER:**

#### **PRINTER -**

We have specified that a process data printer is required, this shall print control process data for each cycle.

#### **PRINTER LOCATION -**

We have specified the most practical location for the control process printer is on the loading side of the sterilizer.

#### **PRINTER FORMAT -**

Time, date, cycle type, time, temperature, pressure operator ID and Pass/Fail indication.

#### **OPERATOR ID -**

We have specified and advise that the process printer should have space for hand written notes, if this is not required change Yes to No.

#### **PRINTER PROCESS DATA PARAMETER UNITS -**

We have specified and recommend, Temperature <sup>0</sup>C and Pressure Pa or mbar, if alternative units are preferred these should be stated in this section.

#### **ARCHIVE DATA STORAGE DEVICE AND LOCATION -**

We have specified for traceability requirements, an archive data storage device is required with the download interface located on the sterilizer, if an alternative location is preferred this information should be stated in this section.

## **Specification Reference: D– 14**

### **PROCESS VARIABLE MONITORING:**

We have listed the specified default process variables to be monitored by the independent instrumentation.

#### **Electronic Storage -**

Electronic storage of independent data is required, the supplier/manufacturer shall submit details of proposed device for consideration.

## **Specification Reference: D– 15**

### **DELIVERY PACKING METHOD:**

We have specified standard packaging however if the GDP envisages storage problems for example due to building works etc. Details of storage requirements should be stated in this section.

## **Specification Reference: D– 16**

### **STAFF TRAINING:**

We have assumed the following four members of staff shall be trained.

If additional personnel are required to be trained, details should be stated against each category in this section.

### **DETAILS OF ROOM AND TRAINING AIDS TO BE MADE AVAILABLE BY PURCHASER -**

We have specified all training aids shall be supplied by the supplier, however operator training shall be within the room which the sterilizer is located.

### **STAFF/USER TRAINING -**

Instruction listed shall be provided, however if additional activities/functions are required these should be stated under User Instructions.

## **Specification Reference: D– 17**

### **DETAILS OF MICROPROCESSOR CONTROLLERS:**

We have specified a traceability interface and reader port be priced as an option. If an alternative preferred method/system is known, details should be stated in this section.

Accessories in connection with specified system should also be detailed to facilitate pricing.

## **Specification Reference: D– 18**

### **WATER SUPPLIES -**

We have specified all sterilizers shall be capable of processing GDP specified dental instruments and items, generating steam from water via a reverse osmosis water plant. Please note this is the preferred method in which the GDP may meet the relevant guidance, both for WD final rinse water and sterilizer clean steam requirements.

### **COST OF UTILITIES –**

We have not completed the list for service utilities as this is practice specific. If information is available to GDP this should be listed, alternatively NOT AVAILABLE should be inserted.