

## APPENDIX 3

### FRAMEWORK AGREEMENT SPECIFICATION INSTRUMENT DECONTAMINATION AND ACCESSORIES

#### 1. Introduction

1.1. This Framework Agreement is for the supply of cleaning & decontamination consumables, accessories, and storage and transport equipment for endoscopes, ultrasound probes and other medical instruments including:

- 1.1.1. Consumables including detergents, disinfectants, wipes, bedside kits and accessories;
- 1.1.2. Equipment for the manual and automated decontamination of ultrasound probes, including but not limited to Ultraviolet and Ultrasound technologies;
- 1.1.3. Equipment for transportation and prolonged storage of endoscopes (excluding drying cabinets); and
- 1.1.4. For absolute clarity this framework does not cover endoscopy cleaning brushes, large capital equipment (such as washer disinfectors and drying cabinets) used for the decontamination and drying process, nor any cleaning or disinfection products where the primary intended use is for environmental cleaning.

1.2. The Framework Agreement is for the following Lots:

Lot Number	Lot Title
1	Cleaning & Disinfection Products, Equipment and Associated Products & Accessories
2	Endoscope Storage & Transportation

1.3. Full technical specifications of the product lines awarded to the Framework Agreement (each a “**Technical Specification**” and together the “**Technical Specifications**”) must be made available to NHS Supply Chain on request during the term of the Framework Agreement.

- 1.3.1. Applicants must notify NHS Supply Chain immediately about any proposed changes to the Technical Specifications throughout the term of the Framework Agreement.
- 1.3.2. If changes to the Technical Specification of any product line awarded to the Framework Agreement mean that the product line no longer meets the minimum requirements outlined in the Specification, NHS Supply Chain reserves the right to exclude that product line from the Framework Agreement.

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1.3.3. NHS Supply Chain reserves the right to request evidence of compliance with the Specification throughout the term of the Framework Agreement.

1.4. This Framework Agreement Specification makes reference to a number of standards, legislation & Guidance. The list of standards, legislation & guidance is not intended to be exhaustive and any relevant standards and legislation which applies to the Framework Agreement (even if not stated) must be complied with by Applicants (together with those listed in this Framework Agreement Specification the "**Standards and Legislation**").

1.5. Product lines must comply with the Standards and Legislation (as amended, extended or re-enacted from time to time).

1.6. Evidence of compliance to the Standards and Legislation must be provided by Applicants awarded to the Framework Agreement ("**Suppliers**") to NHS Supply Chain on request during the term of the Framework Agreement; in the event that sufficient evidence is not provided by Suppliers NHS Supply Chain reserves the right to suspend product lines until such evidence is provided by Suppliers.

## 2. Criteria applicable across all product lines

### 2.1. Standards, Legislation & Guidance

<b>STANDARD, LEGISLATION AND GUIDANCE</b>
<b>EU/GB Biocides Products Regulation 528/2012 + article 95</b>
<b>Registration, Evaluation, Authorisation and Restriction of Chemicals (UK &amp; EU REACH)</b>
<b>HTM 01-01</b> Management and decontamination of surgical instruments (medical devices) used in acute care.
<b>HTM 01-06</b> Management and decontamination of flexible endoscopes.
<b>WHTM 01-01</b> Decontamination of medical devices within acute services.
<b>WHTM 01-06</b> Decontamination of flexible endoscopes
<b>Where products are classed as Medical Devices as per the definition under Medical Devices Regulation 2017/745 the following will apply:</b>
<b>Medical Devices Directive 93/42/EEC (as amended)</b>

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All products must have their CE or UKCA marking evident on the product and/or packaging.

Or

**Medical Devices Regulation 2017/745** (as amended)

All products must have their CE marking evident on the product and/or packaging.

- 2.2. All products provided as part of this framework must not contain an active or preservative of concern as identified by ECHA or Registration, Evaluation, Authorisation and Restriction of Chemicals (UK & EU REACH) or be within their allowable limits. Where there are allowable limits, the ingredient name, Chemicals Abstract Service (CAS) number and concentration must appear on the label.
- 2.3. An SDS must be provided if a substance or a mixture supplied is classified as hazardous under the CLP Regulation (EC) No 1272/2008 and on request applicants must provide such documents to NHS Supply Chain.
- 2.4. If a product line contains phthalates this must be indicated on the packaging of that product line in accordance with Directive 2007/47/EC (amending Directives 90/385/EEC and 93/42/EEC).
- 2.5. Electrical product lines must comply with the requirements of the Directive on waste electrical and electronic equipment (WEEE Directive 2012/19/EU) and the Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS 2 Directive 2011/65/EU).
- 2.6. All product lines and packaging should be latex free where possible. If a product line or any packaging contains or does not contain latex this must be labelled on the product line or packaging (as applicable) to inform the user.
- 2.7. All product lines must be delivered free of charge to a location as directed by either NHS Supply Chain or the customer
- 2.8. Where the intended use is for decontamination of medical devices then the product must be CE/UKCA marked in conformance with Medical Devices Directive 93/42/EEC (as amended) or Medical Devices Regulation 2017/745 (as amended).
- 2.9. Where claimed that the product is effective against Prions (263K scrapie prion, BSE prion and VCJD prion) test data must be provided on request.
- 2.10. Where applicable products must be supplied in sealed, tamperproof containers.

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- 2.11. Product outer packaging (e.g. outer cases, boxes) should be made from recycled materials or suppliers must demonstrate that they are working towards this and to be reviewed on an annual basis.
- 2.12. Product outer packaging (e.g. outer cases, boxes) should be made from recyclable or compostable materials.
- 2.13. Where packaging can be recycled this must be displayed on the packaging.
- 2.14. The product packaging or enclosed information must state/include, as a minimum:
- 2.14.1. Identify the contents of the packaging including any active ingredients;
  - 2.14.2. List any special storage instructions;
  - 2.14.3. Show any shelf-life limits required after opening or reconstituting the product;
  - 2.14.4. Any dilution and dosing information;
  - 2.14.5. Any warnings and precautions including PPE and ventilation requirements (and these must reflect the information on the data sheet).
- 2.15. The label/inner (individual) packaging must state:
- 2.15.1. Expiry Date.
  - 2.15.2. Batch Number.
  - 2.15.3. CE Mark/UKCA Mark.
- 2.16. Training, education and support on the correct use of the products in this framework must be provided in at least one of the following ways, as agreed with the end user/customer:
- 2.16.1. In person on site or a virtual alternative where appropriate.
  - 2.16.2. As end user instructions for use as hard copy literature.
  - 2.16.3. As end user instructions online in a readable/downloadable format.
- 2.17. Training must be provided to the end user/customer at start of product use and follow up training to be offered and provided as agreed with the end user/customer.
- 2.18. Any training materials provided by the supplier to the customer are to remain the property of the supplier unless ownership is expressly transferred to the customer. Updates to training materials must be provided as/when applicable.
- 2.19. All products must be provided with Instructions For Use (IFU) written to comply with UK standards, in English and/or with pictograms.
- 2.20. Product Information to be included in IFU's and Training resources must include as a minimum:
- 2.20.1. Product description and intended use;

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- 2.20.2. How to use the product safely including PPE requirements, chemical spillage detection and ventilation, if applicable;
- 2.20.3. How to use the product effectively;
- 2.20.4. Contraindications/compatibility issues; and
- 2.20.5. Storage instructions for consumables.

2.21. The customer must be able to contact the Applicant with any queries during office hours (i.e. between 9am to 5pm Monday to Friday).

**3. Lot 1 – Cleaning & Disinfection Products, Equipment and Associated Products & Accessories**

3.1. Suppliers of disinfectants and detergents for use in an Endoscope Washer Disinfector (EWD) must provide evidence to the satisfaction of the end user to enable validation of the decontamination process.

3.2. **Automated Disinfectants** - For the disinfection of endoscopes where sterilisation is not possible due to product design and/or temperature limitations.

3.3. The intended use for Endoscope Washer Disinfector (EWD) / Automated Endoscope Reprocessor (AER) disinfectants must be to disinfect endoscopes in an EWD/AER machine.

3.4. Standards, Legislation & Guidance for Automated Disinfectants

STANDARD, LEGISLATION AND GUIDANCE
<p><b>The required disinfection efficacy must be demonstrated using the test standards referenced below and must be:</b></p> <ul style="list-style-type: none"> <li>• Bactericidal,</li> <li>• Mycobactericidal,</li> <li>• Fungicidal,</li> <li>• Viricidal, and</li> <li>• Sporicidal</li> </ul> <p>Where the intended use is in an EWD/AER Machine efficacy of a product must be demonstrated using the test standards referenced in <b>BS EN ISO 15883-4 :2018</b>.</p> <p>Other disinfectants used for reprocessing must be tested according to the European Standard <b>BS EN 14885:2018</b>.</p>

3.5. All endoscope washer disinfector (EWD) disinfectants must be supplied with a minimum 6 months shelf life from;

- 3.5.1. Delivery into NHS Supply Chain, or
- 3.5.2. The end user customer, where deliveries are made direct from the supplier to the customer under the framework.

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3.6. Disinfectants not intended for use in an EWD in this Lot must be supplied with a minimum 12 months shelf life from;

3.6.1. Delivery into NHS Supply Chain, or

3.6.2. The end user customer, where deliveries are made direct from the supplier to the customer under the framework.

3.7. Self-disinfectants that are used to disinfect equipment used in the decontamination process must meet one or more of the following requirements;

3.7.1. Intended for use in EWD/AER in self-cleaning cycle;

3.7.2. Intended for use in a flush system for manual cleaning; and

3.7.3. Intended for use in any other relevant medical equipment.

3.8. **Other disinfectants** – where the intended use is for the decontamination of non-lumened scopes, probes and instruments. Products include:

3.8.1. Wipes;

3.8.2. Foams;

3.8.3. Liquids; and

3.8.4. Tablets

### 3.9. Standards, Legislation & Guidance for other disinfectants

#### STANDARD, LEGISLATION & GUIDANCE

##### **Amendment to the standard requirements:**

Where the product is intended for use without instructions for pre cleaning the testing must be conducted in "dirty" conditions as prescribed in the relevant test standard set out below where applicable.

All Disinfectants used for instrument decontamination must be tested according to the European Standard BS EN 14885:2018 meeting the requirements for

- Bactericidal activity EN 13727 (2/1), EN 14561 (2/2) and
- Yeasticidal activity EN 13624 (2/1), EN 14562 (2/2)

##### **And for wipes in this lot the following:**

##### **BS EN 16615:2015**

Chemical disinfectants and antiseptics. Quantitative test method for the evaluation of bactericidal and yeasticidal activity on non-porous surfaces with mechanical action employing wipes in the medical area (4- field test). Test method and requirements (phase 2, step 2)

##### **Additionally, all Products required to deliver to High Level Disinfection must also be:**

- Fungicidal
- Virucidal (full spectrum) and
- Sporicidal

Fungicidal activity EN 13624 (2/1), EN 14562 (2/2)

Tuberculocidal / Mycobactericidal activity EN 14348 (2/1), EN 14563 (2/2)

Virucidal activity EN 14476 (2/1)

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**EN 17126:2018:**

Chemical disinfectants and antiseptics. Quantitative suspension test for the evaluation of sporicidal activity of chemical disinfectants in the medical area.

**For wipes in this lot: Testing must be conducted with liquid extracted from a wipe, where applicable.**

- 3.10. For all non-automated disinfectant products, contact time (Kill Rate) data must be printed on the packaging and/or IFU. All other efficacy data including log reduction related to the relevant standards (as set out above) must be accessible online as a minimum.
- 3.11. Products must be suitable for the intended use to disinfect non-lumened medical devices and probes, which may include:
- 3.11.1. Transoesophageal echo cardio probes;
  - 3.11.2. Transvaginal ultrasound probes;
  - 3.11.3. Transrectal ultrasound probes;
  - 3.11.4. Intubation endoscopes;
  - 3.11.5. Manometry catheters;
  - 3.11.6. Ultrasound probes;
  - 3.11.7. Nasendoscopes; and
  - 3.11.8. Ophthalmology devices
- 3.12. Where the intended use is for the decontamination of semi-critical medical devices the product and/or process must meet the requirements for high level disinfection.
- 3.13. Where there is a risk of Human Papillomavirus (HPV) on medical devices (e.g. Transvaginal ultrasound probes) the disinfectant must be effective against HPV.
- 3.14. Products designed for the decontamination of semi-critical devices must have an associated tracking and traceability system such as but not limited to labelling or electronic means.
- 3.15. Other disinfectants must be supplied with a minimum of 18 months shelf life from;
- 3.15.1. Delivery into NHS Supply Chain, or
  - 3.15.2. The end user customer, where deliveries are made direct from the supplier to the customer under the framework.
- 3.16. Product packaging must facilitate ease of opening.
- 3.17. In multi-wipe packs the wipes must dispense individually from packaging.
- 3.18. Wipes dispensed from new tubs/canisters or as refills must start dispensing without wasting or contaminating wipes or injuring the operator.

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- 3.19. Packets/containers containing multiple wipes must close/ reseal with a moisture tight seal and stay closed/sealed to prevent drying out of wipes between use.
- 3.20. Applicants are required to support customers decision making around choice of products by providing available compatibility information.
- 3.21. **Automated decontamination** - Equipment for the automated decontamination of ultrasound probes and instruments including Ultraviolet and Ultrasound technologies.
- 3.22. Products designed for the decontamination of semi-critical devices should have an associated tracking and traceability system.
- 3.23. **Detergents** - For the cleaning of medical instruments including endoscopes both manually and in an Endoscope Washer Disinfector. Products include
  - 3.23.1. Gels,
  - 3.23.2. Liquids, and
  - 3.23.3. Sprays.
- 3.24. Standards & Regulations for detergents

<b>STANDARD AND LEGISLATION</b>
<b>Regulation (EC) No 648/2004 on detergents</b>

- 3.25. The intended use for automated detergents must be;
  - 3.25.1. in conjunction with an EWD disinfectant for the cleaning of endoscopes in an EWD or
  - 3.25.2. for the cleaning of medical instruments in washer disinfectors such as: ultrasonic cleaners, trolley washers, and any other related equipment.
- 3.26. Manual cleaning detergents must meet the following requirement:
  - 3.26.1. Intended for the pre-cleaning of instruments including endoscopes; or
  - 3.26.2. Intended for the manual cleaning of instruments including endoscopes post-procedure.
- 3.27. All detergent product lines must be supplied with a minimum 12 months shelf life from;
  - 3.27.1. Delivery into NHS Supply Chain, or
  - 3.27.2. The end user customer, where deliveries are made directly from the supplier to the customer under the framework.
- 3.28. **Pre-clean kits and associated products** - for the first stage in the endoscope cleaning process immediately after clinical use.

3.29. Standards and Regulations for pre clean kits and associated products

**STANDARD AND LEGISLATION**

**Regulation (EC) No 648/2004 on detergents**

3.30. Pre-clean kits and associated products include:

- 3.30.1. Pre-filled or fillable containers, intended for the initial clean, wipe down and flush of an Endoscope;
- 3.30.2. Trays intended for the pre-cleaning of endoscopes; and
- 3.30.3. Stand-alone associated products such as sponges, pots and detergent sachets.

3.31. Kits must be marked as single use.

3.32. Pots and containers must be sufficiently stable (must not fall over when filled) to prevent spillage when full.

3.33. Fillable containers must be marked to show the required fill line and must be visible to the user when in use.

3.34. Where multi-size pot is included as part of the kit, i.e. 250ml to 500ml then both markers must be visible to the end user when in use.

3.35. Containers of fluid and sachets of detergents must be fully sealed so that they will not leak during transport and storage.

3.36. Detergents in kits and sachets must be non or low foaming and must be labelled as such.

3.37. Detergent type must be shown on packaging, i.e. enzymatic or non-enzymatic.

3.38. **Containers for the detachable parts of an endoscope** - These are intended for securing the detachable parts of an endoscope during decontamination and storage.

3.39. **Test kits and strips** - for chemical testing within washer disinfectors and other decontamination machines. These are:

- 3.39.1. Intended to test the concentration of reusable disinfectant in EWD's, Washer Disinfectors and any machine using chemicals for the decontamination process.
- 3.39.2. Intended to test for residual chemicals in EWD's, Washer Disinfectors and any machine using chemicals for the decontamination process.

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- 3.40. **Associated Products** - Additional sundry items used in the decontamination process. Products include:
- 3.40.1. Neutralisers for PA (Peracetic Acid);
  - 3.40.2. Lubricants;
  - 3.40.3. Rinse aids;
  - 3.40.4. Water filters;
  - 3.40.5. Air filters;
  - 3.40.6. Automated Systems – automated system to ensure the correct dosage of detergent/disinfectant is issued;
  - 3.40.7. Central dosing systems;
  - 3.40.8. Flush systems for manual cleaning;
  - 3.40.9. Canister pumps for manual dosing of detergents – manual pump to ensure the correct dosage of detergent is issued;
  - 3.40.10. Scale remover – removes scale and alkaline mineral deposits;
  - 3.40.11. Other (e.g. instrument enhancer, stain remover, mixing jug etc.); and
  - 3.40.12. Low temperature sterilisation accessories.

**4. Lot 2 – Endoscope Storage & Transportation** – equipment and consumables to store, seal and transport endoscopes.

4.1. Standards and Legislation for Endoscope storage & transportation

STANDARD, LEGISLATION & GUIDANCE
<p>Where applicable:  <b>BS EN 16442:2015</b>            Controlled environment storage cabinet for processed thermolabile endoscopes.</p> <p>Where <b>BS EN 16442:2015</b> is not applicable, equipment claiming suitability for prolonged storage must be able to evidence efficacy in maintaining microbiological quality throughout the claimed storage time. This must be available to the customer on request at any point throughout the lifetime of the Framework Agreement.</p>

4.2. All equipment must include a free of charge warranty for a minimum of 12 months (including repair, parts, labour and servicing) from the date of acceptance by the customer.

4.3. **Mobile units and cabinets** – Intended for the transport and prolonged storage of an endoscope, must store and protect endoscopes while being transported within the healthcare environment while maintaining the microbiological quality of cleaned and disinfected endoscopes.

4.4. **Packing and sealing systems** – These systems must sustain the microbiological quality of decontaminated scopes when packed/sealed, transported/stored and up to the point of re-use of the endoscope.

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**4.5. Transportation, storage bags and liners:**

- 4.5.1. Must be intended for the separate storage and transportation of clean and dirty endoscopes; and
- 4.5.2. Must incorporate a means to identify endoscopes as being either clean or dirty (e.g. colour coding, labelling, printing etc.).
- 4.5.3. Must be sterile where used with decontaminated endoscopes

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