ATTACHMENT 4B

FRAMEWORK AGREEMENT SPECIFICATION

OBSTETRICS, GYNAECOLOGY and SEXUAL HEALTH

SECTION A – General Requirements

1. Introduction

1.1. The Framework Agreement is for the supply of Obstetric, Gynaecology, Maternity and Sexual Health products.

1.2. The Framework Agreement is grouped into the following Lots:

Lot Number	Lot Title
1	Obstetrics and Gynaecology. This Lot includes products used in the investigation, treatment and management of gynaecological conditions including related to conception and cessation of pregnancy, management of labour and delivery, maternity and baby care and period products
2	Sexual Health. This lot includes products used in the prevention of sexually transmitted disease, contraception, topical preparation used in treatment and diagnosis as well as simple nonpharmacological devices designed to improve sexual function

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.

- Applicants must notify NHS Supply Chain immediately about any proposed changes to the Technical Specifications throughout the term of the Framework Agreement.
- 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.
- 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 refers to several standards and legislation. The list of standards and legislation 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 during the tender submission and upon 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.

1.7. The Provider must ensure that any product recall issued by the Department of Health and Social Care or any alert from the NPSA is to be actioned in accordance with relevant guidelines and reported to the Participating Customers Authorised Person in writing.

1.8. All product lines must be delivered free of charge to a location as directed by either NHS Supply Chain or the customer.

2. Criteria applicable across all product lines

Standards and Legislation

2.1. Files uploaded as part of the tender submission must be clearly named with the directive / standard to which they relate as well as clearly identifying which product / products they cover.

STANDARDS AND LEGISLATION
Where products are classed as Medical Devices as per the definition under Medical Devices Regulation 2017/745 the following will apply: **Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002)** 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 or UKCA marking evident on the product and/or packaging. **BS EN ISO 20417:2021 (previously BS EN 1041:2008 +A1:2013.)** Medical devices. Information to be supplied by the manufacturer. **BS EN ISO 15223-1:2016 or BS EN ISO 15223-1:2021** Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. Where applicable products must conform to: **BS EN 62366-1:2015+A1:2020** Medical devices. Application of usability engineering to medical devices. Where products are sterile, they must comply with either applicable standard below or equivalent international standard to designate device as sterile. **BS EN 556-1-2001** Sterilization of medical devices. Requirements for medical devices to be designated "STERILE". Requirements for terminally sterilized medical devices. **BS EN556-2-2015** Sterilization of medical devices. Requirements for medical devices to be designated "STERILE". Requirements for aseptically processed medical devices. Where a product is sterilised an applicable validated sterilisation and routine control process must be applied; for example: **BS EN ISO 14937:2009** Sterilization of health care Sterilization of health care products. **BS EN ISO 11137 series** Sterilization of health care products. Radiation

BS EN ISO 17665-1:2006
Sterilization of health care products. Moist heat. Requirements for the development, validation and routine control of a sterilisation process for medical devices

Where applicable, any digital connectivity, software, associated apps and modems must meet the requirements of the customer alongside provision of required training and ongoing support. Customers may use the NHS Digital Technology Assessment Criteria for health and social care (DTAC) for assessment of the devices and it is recommended that suppliers familiarise themselves with these criteria to meet clinical safety, data protection, technical security, interoperability and usability and accessibility standards.

2.2. On request applicants must provide NHS Supply Chain with Safety Data Sheets (SDS) for all products that fall under REACH (Registration, Evaluation, Authorisation, and restriction of Chemicals) 2007 –more specifically, an SDS must be provided if a substance or a mixture supplied is classified as hazardous under the CLP Regulation (EC) No 1272/2008.

2.3. 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 Directive 2002/95/EC).

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. If a product contains DEHP this must be stated on the individual product packaging or instructions for use (IFU) and/or made available to NHS Supply Chain or end user on request.

2.6. All product lines and packaging should be latex free where possible. If a product line or any packaging contains latex this must be labelled on the product line or packaging (as applicable) to inform the user.

2.7. Under the Medical Devices Directive, where a product is:

- Class I (non-Sterile) - Declaration of conformity is to be provided
- Class I Sterile, Class A Measuring, Class IIa, Class IIb & Class III - CE Certificate from a Notified Body to be provided

2.8. During the term of the Framework Agreement Applicants must make NHS Supply Chain aware of any awarded product line that is classed by the MHRA as a Medicinal Product.

2.9. GS1 standards are a fundamental part of the Department of Health (DH) strategy for building a safer and more efficient NHS - standards for barcoding to uniquely identify places, products and people (patients and staff). Compliance of the GS1 coding standard is required and fully implemented on Product/Packaging labelling depending on Classification between 2018 and 2020. Further Information can be found at;

- https://www.gs1uk.org/sites/default/files/gs1_uk_compliance_peppol_timeline_1.pdf
- https://www.gov.uk/government/publications/nhs-e-procurement-strategy

All products subject to a warranty (free of charge; including repair, parts, labour and servicing) from the date of acceptance by the customer, must state the length of warranty. Any warranties over 12 months shall be clearly identified.

Must state details strictly necessary to identify the device for the user on the individual product packaging

2.10. Lot number and expiry date must be stated on the individual product packaging.

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

2.12. For ordering purposes an identifier, for example reference / manufacturing product code (MPC), must be stated on the individual product packaging and/or unit of issue packaging.

2.13. Product must be robust enough to resist breakage when used as directed by manufacturer.

2.14. Instructions for storage and disposal of the device must be contained on the individual product packaging and/or IFU and/or made available to NHS Supply Chain or end user on request.

2.15. Information on the product constituent's raw material/s must be made available to NHS Supply Chain or end user on request to support with customer recycling requirements.

2.16. Information on country of origin must be made available to NHS Supply Chain or end user on request.

2.17. Information on weight of product must be made available to NHS Supply Chain or end user on request to provide trust with weight waste information.

2.18. External unit of issue product packaging must be made of recyclable material where possible.

2.19. Where external unit of issue packaging can be recycled this must be displayed on the packaging.

2.20. Where a product is reusable, the product must be able to be cleaned to prevent cross contamination.

2.21. Where applicable have available cleaning / decontamination instructions which must be stated on the individual product packaging or IFU and/or made available to NHS Supply Chain or end user on request.

2.22. Where applicable, products must be supplied sterile and individually wrapped.

2.23. Individual packaging must be of durable construction preventing the product from being pushed through or tampered with and must not tear or rip apart during transportation and storage, to avoid damage to the product and / or breaches of product sterility and to reduce risk of plastic packaging being a foreign body when device being used.

2.24. Where applicable, the product packaging must include a non-adherent tab which allows the product packaging to be opened at one end maintaining sterility.

2.25. Where applicable, the word single use and / or symbol must be depicted on the individual product packaging to inform the user of the product's single use status in line with labelling (ISO 15223).

2.26. Where applicable for products that are sterile, the transparent side of the individual packaging must allow visualisation of the contents.

2.27. If MRI compatible it must be stated on the individual product packaging and / or unit of issue packaging.

2.28. During the term of the Framework Agreement Applicants must make NHS Supply Chain aware of any awarded product line that is classed by the MHRA as a Medicinal Product.

2.29. All product line(s) must be supplied with a minimum 12-month shelf life on receipt of delivery.

2.30. All product lines 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.

2.31. All product lines must be delivered free of charge to a location as directed by either NHS Supply Chain or the customer.

2.32. IFUs must be provided for each medical device and must be written in English or pictograms and included on the individual product packaging and/or within the unit of issue (UOI) and/or made available to NHS Supply Chain or end user on request.

2.33. Training and implementation must be provided on request and in accordance with trust requirements through mutual agreement. This could be, for example, providing ongoing support including pre-implementation education, supplier support and implementation guidance, bespoke clinical training, eLearning, and post-implementation support.

2.34. Training and education around the maintenance, testing and calibration of the devices must be provided on request and in accordance with trust requirements through mutual agreement.

2.35. Where the product is to be used only in a specific part of the body, instructions/guidance must be provided with the individual product in English and on the product where possible, including diagrams if feasible.

2.36. Any cautions / warnings / contraindications to use must be provided in IFU.

For re-useable products, (multi patient use or single patient use) cleaning instructions and care guidance must be supplied with the product.

Where size options exist, this should be displayed. When generic terms are used, it is desirable that they be accompanied by sizing information. E.g., Medium, 40 to 50cm.

3. Environmental Considerations

3.1. Due consideration shall be given to the environmental impact of the products supplied under this framework. Continuous improvement techniques to identify and reduce the carbon footprint shall be employed.

3.2. On request, the Supplier shall provide documentary evidence to demonstrate compliance with the requirements of the Packaging (Essential Requirements) Regulations 2015 (as amended) which implements the EC Directive on Packaging and Packaging Waste (94/62/EC) in the UK, and which requires, packaging to be minimised, recoverable, and to not exceed by weight specified concentrations of heavy metals. Further guidance can be found on the Department of Trade and Industry's website at https://www.gov.uk/guidance/packaging-waste-become-a-packaging-producer-compliance-scheme-pcs

3.3. Product literature shall identify information pertaining to the disposal; re-use; refurbishment or recycling of products.

4. Product Evaluations

4.1. Any product trials / evaluations agreed to take place by both the Provider and Trust will be at no charge to the Trust. For the avoidance of doubt this includes, but is not limited to, no delivery charges, no loan kit charges, no cost of training etc. We reserve the right to evaluate products post tender.

4.2. Where research/evaluation has been completed the full details, methodology and results of the investigation should be made available and may be used by any member Trust in their analysis and consideration of offers, upon award of this Agreement.

4.3. The Provider must inform NHS Supply Chain and trusts in writing of any proposed changes to the specification of existing products for the goods being supplied against the contract, including proposed changes to packaging quantity or format, or product coding, for consideration by the Trust. Notification of any such proposals shall be made at least three months prior to the proposed implementation date of any changes.

SECTION B – Specific Requirements

1. Lot 1

LOT 1 Obstetrics and Gynaecology. This Lot includes products used in the investigation, treatment and management of gynaecological conditions including related to conception and cessation of pregnancy, management of labour and delivery, maternity and baby care and period products		
Section	Products	Description
1.1	Assisted Reproduction	Assisted reproductive technology (ART) is used to increase the incidence of conception. It includes fertility treatments that handle both eggs and sperm. This lot is for the consumables and sundries associated with ART, and for conception aids used to assist in the achievement of a pregnancy
1.2	Obstetrics and Baby Care	Products associated with care of the expectant mother during pregnancy, labour and immediately post-partum, and products associated with care of the new-born baby for the period spent in hospital.
1.3	Birth Pools and Accessories	Includes products and accessories used to assist with a water birth
1.4	Gynaecology	Includes products associated with monitoring and maintaining female pelvic health
1.5	Period Products	Products associated with managing or absorbing menstrual bleeding, post-partum bleeding and vaginal discharge

1.1. **Assisted Reproduction**

Assisted reproductive technology (ART) is used to increase the incidence of conception. It includes fertility treatments that handle both eggs and sperm. This is for the consumables and sundries associated with ART, and for conception aids used to assist in the achievement of a pregnancy.

- Must be provided with instructions for use written in English.
- Up to date Quality Management forms must be available on request for products used in assisted conception units.
- Must be provided sterile.
- Must be single use.
- Must display ingredients on product packaging where relevant.

1.1.1. **Hormone Free Conception Aids:** Devices and products intended to improve the likelihood of natural conception. Does not include digital app based cycle monitoring.

- Instructions for use must include diagrams to demonstrate fitting procedure.

1.1.2. **Sperm Collection & Processing**: products / devices used for semen collection and processing for the purposes of analysis and / or assisted reproduction procedures. Includes but not limited to sperm filtration systems, counting chambers, sperm rinse and sperm straws. Does not include products used in the Pathology laboratory.

1.1.2.1. **Sperm Separation System:** An assembly of devices incorporating filters that separate motile sperm from nonmotile sperm and seminal fluid/plasma for use in intrauterine insemination and other forms of assisted reproduction techniques

1.1.3. **Media & Oil**: A solution that provides a physiological environment for the retrieval, culture, maintenance, transfer, and/or storage of human sperm, harvested oocytes (eggs), and/or resulting embryos associated with the method of in vitro fertilization (IVF). The solution typically contains various combinations of salts, carbohydrates, amino acids, enzymes, hormones, albumin, vitamins, and/or drugs (e.g., antibiotics). Includes but not limited to preparation, retrieval, handling, culture, transfer, cryopreservation.

1.1.4. **Micromanipulation Pipettes**: long, thin tubes made of glass or plastic for the manual withdrawal, transfer, and injection of minute volumes of fluid materials (e.g., microlitres or smaller).

1.1.5. **Catheters and Needles:**

1.1.5.1. **Embryo Transfer Catheter**: designed for use in assisted reproduction procedures. Includes but not limited to embryo transfer, oocyte retrieval, intrauterine insemination (IUI).

1.1.5.2. **Oocyte Aspiration Needle**: A sterile, sharp bevel-edged, hollow tubular metal instrument specifically designed to penetrate ovarian follicles and aspirate oocytes (eggs) typically during the harvesting phase of an in vitro fertilization (IVF) procedure. The device may include aspiration tubing attached to its proximal end.

1.1.5.3. **Intrauterine Insemination Catheter (IUI):** A device or collection of devices that includes a flexible polymer tube intended to be used primarily to transfer gametes (eggs or sperm) and/or embryos into the female reproductive tract for the purpose of assisted reproduction.

1.1.6. **Cryopreservation**: products designed specifically for assisted reproduction vitrification & warming procedures. Includes but not limited to straws (e.g., embryo, sperm, oocyte), tubes, vitrification kits, warming kits. Does not include media / oil.

1.1.6.1. **Straws**: A long, thin, tubular sterile device in the form of a straw used for the placement and storage of human biological samples such as embryos, oocytes, sperm, and human tissue in liquid nitrogen (LN_2) or in the volumes of vapour phase LN_2 in a liquid nitrogen container.

- Must be made of materials to withstand storage in LN_2
- May include a sliding plug, or a permeable membrane plug to hold the sample.

1.1.6.2. **Vitrification Carrier**: A sterile, plastic device intended to be used during an assisted reproduction vitrification (cryopreservation) procedure to hold a small volume of vitrification media containing a biological specimen (e.g., egg, embryo) to vitrify (cryopreserve) the specimen, thereby avoiding specimen immersion/contact with LN_2.

- Must be made of materials to withstand storage in LN_2

1.1.6.3. **Accessories**: products designed specifically for assisted reproduction procedures not covered in other sublots. Includes but not limited to dishes, pipettes.

1.2. Obstetrics & Baby Care

Products associated with care of the expectant mother during pregnancy, labour and immediately post-partum, and products associated with care of the new-born baby for the period spent in hospital.

- Must be provided with instructions for use written in English.
- Includes single use and reusable products / devices / instruments.

1.2.1. **Birthing Aids**: products to help mothers find their most comfortable positions during labour and delivery. Includes, but not limited to birthing pillows and their accessories (such as a birthing ball pump). This does not include birthing couches or birthing stools.

- Must be reusable.
- Must be wipe clean or suitable for washing.
- Instructions for use must include cleaning information.

1.2.1.1. **Birthing Pillow**: A soft pillow, pad, or sack filled with small beads (Sacco sack), or an inflatable cushion, intended to provide positional support and comfort for a pregnant woman during labour and/or childbirth

1.2.2. **Foetal Dopplers**: a portable device assembly consisting of a measuring and display unit and probe designed to non-invasively detect foetal heart beats using ultrasound / doppler technology. Includes, but not limited to hand-held or table-top devices, supplied with or without probe, with fixed or interchangeable probe. Included 2mHz and 3mHz.

- Must be portable.
- Must be battery operated.
- Desirable to have waterproof probe in the range.
- Desirable to be rechargeable.
- Desirable to have function to connect to headphones.
- State if probe fixed or interchangeable.

1.2.2.1. **Foetal doppler, audio**: heart rate transmitted by speaker only.

1.2.2.2. **Foetal doppler, digital**: heart rate transmitted by speaker plus digital display.

Standards for Dopplers	
BS EN 61206:1995	Ultrasonics. Hand-held probe Doppler foetal heartbeat detectors. Performance requirements and methods of measurement and reporting.

1.2.3. **Foetal monitoring:** Products / devices designed for monitoring wellbeing of the baby during pregnancy, labour, and post-delivery. Includes, but not limited to amnioscope, amniocentesis needle, chorionic villous sampling needle, foetal blood sampling, intrauterine pressure monitoring catheter, umbilical catheter, umbilical catheter securement system.

1.2.3.1. **Transcervical Amnioscope**: An endoscope with a rigid inserted portion intended for the visual examination of the foetus while in the amnion. Inserted via the vagina, through the maternal uterine cervix and into the amniotic cavity. Single use device must be provided sterile.

- Reusable device must be suitable for sterilisation.

1.2.3.2. **Amniocentesis Needle**: designed to aspirate a sample of amniotic fluid from the amniotic sac, via a transabdominal approach, for analysis. Must be provided sterile.

- Must have echogenic tip.
- Desirable to have a range of gauges.

1.2.3.3. **Chorionic Villous Sampling Needle**: A slender, sharply pointed metal tube intended for transabdominal chorionic villus sampling (CVS) to obtain intrauterine specimens of the chorionic villi for genetic testing to detect chromosomal

disorders in the foetus during the first trimester of pregnancy. May include connectors, tubing and aspiration syringe.

- Must be provided sterile.
- Must have echogenic tip.
- Can be curved or straight.
- Desirable to have a range of gauges.

1.2.3.4. **Foetal Blood Sampling Kit**: A collection of devices intended to collect blood from the foetal scalp during labour or obstetric endoscopic procedures. It typically includes instruments to pierce the scalp and obtain the blood sample such as a syringe/handle, needles/blade, a plastic cone, capillary tube, tubing, and possibly supplies such as swabs and disinfectant solutions.

- Must be provided sterile.
- Must include scalpel and capillary type tube as minimum.
- Desirable to have a range of sizes suitable for different sample analysers.

1.2.3.5. **Foetal Blood Sampling Knife**: A manual instrument with a short blade intended to be used to obtain foetal blood transcervically through an endoscope by puncturing foetal skin, after which blood is drawn into a heparinized tube.

- Single use device must be provided sterile.
- Reusable device must be suitable for sterilisation.

1.2.3.6. **Intrauterine Pressure Monitoring Catheter**: A flexible tube with a pressure sensor, transducer, and/or thermistor located at its distal tip, used for intrapartum transcervical measurement of the intrauterine and amniotic pressures. It is attached at its proximal end via a signal cable to an external monitor that displays the pressure/temperature values, and is used to monitor the intensity, duration, and frequency of uterine contractions during labour. It may also be used for fluid infusion and sampling of amniotic fluid. It is typically made of plastic and/or silicone, and may include a catheter introducer/sheath.

- Must be provided sterile.

1.2.3.7. **Umbilical Catheter**: A very thin flexible tube designed for umbilical blood vessel access in neonates, typically for the infusion of fluids. It is used mainly in arterial catheterization procedures, but venous catheterization is also possible. It will typically have a double or triple lumen to enable additional concurrent functions such as vital sign monitoring and blood sampling (e.g., for blood gas analysis).

- Must be provided sterile.
- Must be single use.
- Must be radiopaque.
- Must have luer lock connector(s).
- Desirable to have a range of sizes. Lengths, gauges, and number of lumens

Standards for Umbilical Catheters	
BS EN ISO 80369-7:2021	Small-bore connectors for liquids and gases in healthcare applications — Connectors for intravascular or hypodermic applications.

1.2.3.8. **Umbilical Dilator:** Device to stretch umbilical cord.

- Single use device must be provided sterile.
- Reusable device must be suitable for sterilisation.

1.2.3.9. **Umbilical Catheter Securement System**: designed to secure umbilical cord catheters while protecting the catheter insertion site.

- Must be single patient use.
- Must be provided sterile.

1.2.4. **Induction of labour:** Non-pharmacological products / devices designed to induce labour artificially by a healthcare professional. Includes, but not limited to cervical ripening products, amniotic hook.

1.2.4.1. **Amniotic Hook**: A surgical instrument used to rupture the amniotic membrane to assist in childbirth, without causing injury to the mother or foetus. It is typically long and shaft-like and terminates in a rounded nose with a sharp hook. It is made of plastic materials and may be straight or curved to follow the natural contours of the birthing canal into which it is inserted.

- Single use device must be provided sterile.
- Reusable device must be suitable for sterilisation.

1.2.4.2. **Cervical Ripening Device:** Designed to induce labour by generating mechanical pressure to dilate the cervix.

1.2.4.3. **Balloon**: a flexible, tube-like device, with inflatable balloons, designed to dilate the cervical canal after insertion through the cervical os and expansion of the balloons.

- Must be provided sterile.
- Desirable to be provided with stylet.

1.2.4.4. **Hygroscopic / Osmotic**: a plug of expansible material intended to dilate the uterine cervix by gradually swelling to several times its original diameter through the absorption of moisture from the cervix.

- Must display ingredients on product packaging.

1.2.5. **Assisted Delivery**: products / devices designed for use by a healthcare professional to help a mother deliver their baby. Includes, but not limited to obstetric forceps, vacuum assisted devices, inflatable sleeve delivery devices, foetal head disimpaction devices, episiotomy scissors. These can be single patient use or reusable.

1.2.5.1. **Obstetric Forceps**: a scissors-like obstetrical instrument intended specifically to assist the birth of the foetus during difficult vaginal births.

- Must be metal.

1.2.5.2. **Vacuum Assisted Device Single Use:** a suction cap intended to be applied to the scalp of a foetus to facilitate vaginal or Caesarean section delivery by traction.

- Can be with or without traction force indicator.
- Desirable to have different shaped cups in the range.

1.2.5.3. **Vacuum Assisted Device Reusable**: a suction cap intended to be applied to the scalp of a foetus to facilitate vaginal or Caesarean section delivery by traction.

- Can be with or without traction force indicator.
- Desirable to have different shaped cups in the range.

1.2.5.4. **Inflatable Sleeve**: designed to facilitate delivery of a foetus during vaginal childbirth via an inflatable sleeve which surrounds the foetal head and enables application of traction around the head of the foetus.

- Must be provided sterile.

1.2.5.5. **Foetal Head Disimpaction Device**: designed to assist with elevating the foetal head out of the pelvis to facilitate delivery during Caesarean section.

1.2.5.6. **Balloon Cephalic Elevation Device**: an expandable capsule/balloon intended to push the foetal head out of the pelvis to facilitate delivery during Caesarean section, typically for those requiring a Caesarean section at full dilation or after a failed instrumental vaginal delivery. It is inserted into the posterior vagina between the foetal head and the adjacent pelvic bone and inflated with saline from a connected syringe and tubing.

- Must be provided sterile.

1.2.5.7. **Vacuum Release Device**: inserted into the vagina to help air flow around the foetal head to break the vacuum and release the foetus.

- Must be provided sterile.

1.2.5.8. **Episiotomy Scissors**: a hand-held, manual, obstetrical, surgical instrument intended to cut the outlet of the vagina in childbirth to facilitate the birth of the. It comprises two pivoted blades that are usually provided with a finger and thumb ring-handle and which cut with a shearing. May be straight, curved or angled and varied sizes; may be serrated.

- Reusable devices must be suitable for sterilisation.
- Single patient use devices must be provided sterile.

1.2.6. **Pain Relief (non-pharmacological):** products / devices designed to manage pain during labour, delivery, and the post-natal period.

1.2.6.1. **Maternity TENS Pads:**
- Specific to maternity TENS machines only.

1.2.7. **Post-Partum Treatment**: products / devices designed to treat side-effects or complications of labour and delivery in the immediate post-partum period. Includes, but not limited to assisted suturing devices, post-partum haemorrhage management devices / systems.
- Must be provided sterile.
- Must be single patient use devices.

1.2.7.1. **Assisted Suturing Device**: designed to facilitate suturing of tears post-partum.

1.2.7.2. **Post-Partum Haemorrhage Treatment:** Devices / Systems designed to control post-partum bleeding.

1.2.7.3. **Balloon**: A sterile, flexible tube with an inflatable balloon at its distal end intended to be inserted into the uterus and distended with a medium (e.g., sterile water, medical air, or other appropriate gas) to reduce postpartum bleeding with pressure. It may have an additional balloon inflated in the upper vagina to seal the uterine cavity.

1.2.7.4. **Chitosan Haemostatic:** A non-bioabsorbable device that includes chitosan (a polysaccharide derived from chitin, the structural element in the exoskeleton of crustaceans) as a principal component, intended to be applied exclusively by healthcare professionals in a clinical setting to produce a rapid haemostasis by forming a robust plug of gel which is removed after use.

1.2.7.5. **Vacuum**: A sterile, flexible tube with a fenestrated loop at its distal end intended to be connected to a vacuum supply and inserted into the uterus to reduce postpartum bleeding through aspiration of blood/debris and induction of uterine contractions. It may have an additional balloon inflated in the upper vagina to seal the uterine cavity.

1.2.8. **Umbilical Cord Care:** products / devices designed for use by a healthcare professional to facilitate the safe and effective medical separation of new-born from mother and treat any complications that may arise. Includes, but not limited to umbilical cord clamps and rings, umbilical cord clamp removers, silver nitrate applicators.
- Must indicate if sterile or non-sterile.

1.2.8.1. **Umbilical Cord Clamps**: A hand-held manual surgical instrument designed to temporarily compress the umbilical cord immediately after birth. It is used before cutting or ligating (e.g., with a clip) the cord, and is intended to enable aseptic haemostasis. It is typically made of plastic material and may incorporate features such as serrations on the contact area and/or a security lock.

1.2.8.2. **Umbilical Cord Clamp Removers**: a surgical instrument designed to remove an umbilical cord clamp that has been applied to a patient. It typically operates by either opening the clamp's locking mechanism or by cutting the clamp.

1.2.9. **Baby Care & Obstetric Accessories:** products designed for care of the new-born while in hospital. Includes, but not limited to changing mats, changing tables, baby baths, phototherapy eye shields, heel warmers. Does not include baby shampoo, baby body wash, or baby lotions / creams. Obstetric Accessories, includes, but not limited to midwife bag, modesty blanket, tape measure and panniculus retractor.

1.2.9.1. **Changing Mats:**

- Reusable products must be wipe clean.
- Instructions for use must include cleaning information.
- Must have raised edges.

1.2.9.2. **Changing Tables:**

- Wall mounted versions must have central adjustable strap to secure baby.
- Free standing versions must have raised sides.
- Must be wipe clean.
- Instructions for use must include cleaning information.

1.2.9.3. **Baby Baths**: designed to hold baby safely while they are being washed.

- Instructions for use must include cleaning information.

1.2.9.4. **Phototherapy Eye Shields:** designed to shield the infant's eyes from UV phototherapy treatment.

- Must be single patient use.

1.2.9.5. **Heel Warmers**: designed to increase blood flow safely and comfortably to the infant's heel area.

- Must be single patient use.

1.2.9.6. **Midwife Bag**: for midwives to store and carry their equipment.

- Must have a handle / carry strap.
- Desirable to be wipe clean.

1.2.9.7. **Tape Measures**: A flexible device intended to be used in a clinical setting to establish an accurate measurement of length greater than a standard ruler (e.g., general anatomical measurements of newborn babies). It is typically made of silk-coated paper and marked in units of length (i.e., inches and/or millimetres);

- Must be single patient use.
- Measurements must include centimetres.
- Scale must be in millimetre units (0.1cm) as minimum.
- Desirable for space to write on to record infant name.
- Please indicate if for abdomen or infant or both

1.2.9.8. **Surgical Adhesive Panniculus Retractor**: adhesive device for retraction of the panniculus during surgical procedures.

- Designed for intraoperative use.
- Must be single patient use.
- Must be printed with instructions for correct placement and application.
- Must be shaped.

1.3. **Birth Pools & Accessories**

Products and accessories used to assist with a water birth.

- Must be provided with instructions for use written in English.

1.3.1. **Inflatable Birthing Pool**: a reusable pool intended to be filled with heated water for use before and/or during childbirth. It may be used to deliver the baby under water and/or to provide a comfortable environment for the expecting mother prior to birth.

- Must be supplied clean.

1.3.2. **Birth Pool Accessories**: for use with birthing pool. Includes, but not limited to debris nets, hoses, pumps, liners, mirrors, thermometers.

1.3.2.1. **Water Removal Pump**: used for emptying the pool of water.

1.3.2.2. **Inflation Pump**: for inflating and / or deflating the birthing pool.

1.3.2.3. **Debris Net**: used for sifting and filtering the water in the birthing pool.

1.3.2.4. **Hose**: used for filling and / or emptying the birthing pool with water.

- Must be food grade.

1.3.2.5. **Liner**: used to line the birthing pool to reduce cross contamination

- Must be single use.

1.3.2.6. **Mirror**: used to view baby while mum can remain in the birthing pool.

- Desirable to be acrylic.

1.3.2.7. **Thermometer**: a device designed for measuring the temperature of water in the birthing pool. It may be held in the bath water by the healthcare attendant or suspended over the edge of the bath, for partial submersion in the water for the duration of the birthing session.
- Must be fully submersible.
- Desirable for it to float.

1.3.2.8. **Kneeling Pad:** suitable for use in a birthing pool.

1.3.2.9. **Non-Slip Matting**: suitable for use in a birthing pool**.**

1.4. **Gynaecology**

Products associated with monitoring and maintaining female pelvic health.
- Must be provided with instructions for use written in English.

1.4.1. **Hysterosonography**: products/devices used during medical imaging procedures visualising the uterus & fallopian tubes. Includes, but not limited to hysterosonography catheters.
- Must be provided sterile.

1.4.1.1. **Hysterosonography Catheters**: A flexible tube designed for the intrauterine injection of an opaque tracer medium, to facilitate radiography of the fallopian tubes/uterus (salpingography/ hysterosalpingography), and/or a saline solution, to enhance transvaginal ultrasonography (TVUS) [saline infused sonography (SIS)/ hysterosonography]. It is typically a dual-lumen tube, with a non-latex inflatable cuff (balloon), pad or cap near the distal tip intended to seal the cervix and may include devices dedicated to catheter function (e.g., stylet, syringe).

1.4.2. **Tissue & Cell Sampling**: products / devices used to obtain gynaecological samples for pathology testing. Includes, but not limited to cervical samplers, endometrial samplers, swabs.

1.4.2.1. **Cervical Sampler**: a device with bristle-like projections designed to obtain a cervical biopsy of a suspicious area or visible exocervical lesions detected during a vaginal examination for the purpose of obtaining a tissue diagnosis from a woman with intraepithelial disease. May include, diamond shaped broom, cylindrical brush, spatula, spoon (not exhaustive).
- Must be single use.

1.4.2.2. **Endocervical Sampler**: devices designed to remove superficial tissue from the mucous membrane lining the cervical canal. May be retractable.
- Single use items must be supplied sterile.
- Reusable items must be suitable for sterilisation.

1.4.2.3. **Endometrial Sampler**: an aspiration curette designed to remove superficial tissue from the mucous membrane lining the cervical canal (endometrium) through manually powered suction.

- Must be provided sterile.
- Must have a method of suction to obtain tissue sample, such as piston or syringe.

1.4.2.4. **Cervical Swab**: a hand-held manual device, also known as a cotton bud or swab, in the form of a stick with a single- or double-ended absorbent tip (e.g., cotton pledget), to take cervical specimens from a patient.

1.4.3. **Uterine Devices**: products / devices used on or within the uterus during gynaecological procedures. Includes, but not limited to Spackman cannulas, uterine manipulators, uterine aspiration, uterine curettes, uterine sounds +/- dilators.

- Single use items must be supplied sterile.
- Reusable items must be suitable for sterilisation.

1.4.3.1. **Spackman Cannula**: a hand-held manual surgical instrument designed to atraumatically mechanically manipulate the position of the uterus during a gynaecological intervention (e.g., laparoscopy) to enable uterine control and improved visibility of the pelvic anatomy. This is a dual-use instrument combining uterine manipulation and fluid injection.

1.4.3.2. **Uterine Manipulators**: a hand-held manual surgical instrument designed to atraumatically mechanically manipulate the position of the uterus during a gynaecological intervention (e.g., laparoscopy) to enable uterine control and improved visibility of the pelvic anatomy. With or without injection port.

1.4.3.3. **Uterine Curettes**: a tubular, semi-rigid, hand-held device used to scrape the lining of the uterus for the removal of tissue during a gynaecological procedure, typically for the removal of an early or non-viable embryo/foetus. The device typically has a rounded blunt nose and an opening(s) with a blunt scraping edge(s) at the distal end. It is connected at the proximal end to tubing and a suction source, typically an abortion suction system, which provides regulated suction. Can be flexible or rigid.

- Can be straight or curved.
- Desirable to have a range of sizes.

1.4.3.4. **Uterine Sounds +/- Dilators**: a hand-held manual instrument designed to measure and/or explore the internal depth or length of the uterus, cervix, and/or vagina. It is a slender hollow or solid cylindrical instrument made of metal or plastic typically with graduations of length displayed along its working end. It is typically available in a range of sizes and flexibilities.

1.4.4. **Forceps, Scissors & Sponge Holders**: Reusable or single use gynaecology specific devices used in surgical and / or medical interventions. Includes, but not limited to vulsellum forceps, tenaculum forceps, uterine scissors, sponge holders, vulvar biopsy forceps.

1.4.4.1. **Gynaecology Forceps**: a hand-held manual surgical instrument with hooks at the distal end used for grasping and/or manipulating uterine tissue during a surgical intervention or examination of the uterus and associated structures (e.g., cervix). It typically has a scissors-like, self-retaining design with ring handles. Includes but not limited to Caesarean, Cervical Punch Biopsy, Hysterectomy, Ovum, Parametrium, Polyp, Tenaculum, Vulsellum, Vulvar Biopsy.

1.4.4.2. **Cervical Biopsy Punch**: a hand-held manual surgical instrument designed to obtain soft-tissue biopsy specimens from the cervix for histopathological examination; it is not intended for endoscopic or catheterized access. It is a metallic forceps-like instrument with a distal mechanism designed to bite/punch the biopsy sample and hold it for extraction when the handles are squeezed together.

- Reusable devices must be suitable for sterilisation.
- Single patient use devices must be provided sterile.

1.4.4.3. **Vulvar Biopsy Forceps**: a hand-held manual surgical instrument designed to obtain soft-tissue biopsy from the vulva; it is not intended for endoscopic or catheterized access.

- Single use items must be supplied sterile.
- Reusable items must be suitable for sterilisation.

1.4.4.4. **Gynaecological Scissors**: a hand-held manual surgical instrument designed to cut tissues during a gynaecological surgical procedure; it is not intended for obstetric use. It is comprised of two pivoted shearing blades with finger and thumb ring-handles (i.e., not pinch-grip design) whereby the shearing action is directly adjacent to the handles (i.e., not alligator or endoscopic design).

1.4.4.5. **Cervix Stabilisation Device:** a manual hand held device that uses suction to stabilise the cervix for gynaecological procedures.

- Single use items must be supplied sterile.
- Reusable items must be suitable for sterilisation.

1.4.4.6. **Sponge Holders**: a hand-held manual surgical instrument designed to hold sponges & swabs during a gynaecological surgical procedure.

- Must be able to fit through a vaginal speculum.

1.4.5. **Pessaries & Bladder Support Devices:** devices placed in the vagina to support the bladder, vagina, uterus and / or rectum as a non-surgical method for the treatment of pelvic organ prolapse and / or stress, urge or mixed urinary incontinence.

1.4.5.1. **Pessaries**: A device made of rubber or soft plastics designed for insertion into the vagina to hold the uterus, bladder and/or rectum in place and help prevent prolapse either as a permanent or temporary treatment; it is not dedicated to bladder-only support. It is available in a variety of shapes (e.g., rings, stems) and sizes and fitted individually. Ranges can include, but are not limited to Ring, Gellhorn, Shaatz, Cube, Dish, Cup, Hodge, Shelf.

- Must be single patient use.
- Indications for use must include care and cleaning information.
- Must be available in a range of sizes to meet patient needs.

1.4.5.2. **Bladder Support Device**: a non-surgical treatment dedicated to bladder-only support for stress, urge or mixed urinary incontinence.

- Must be single patient use.
- Indications for use must include instructions for patient self-use and care and cleaning information.
- Must be available in a range of sizes to meet patient needs.

1.4.5.3. **Pessary Fitting Set**: to help healthcare professionals determine accurate pessary type and size prior to prescribing a pessary to a patient.

- Indications for use must include care and cleaning information.

1.4.6. **Cervix Devices**: products / devices used on or within the cervix during gynaecological procedures. Includes, but not limited to dilators and os finder.

- Reusable devices must be suitable for sterilisation.
- Single use devices must be provided sterile.
- Must be available in a range of sizes.

1.4.6.1. **Word Catheter**: A short (e.g., 5 cm) plastic tube designed to form a tract from either of the two small reddish glands (Bartholin's glands), one on each side of the vaginal orifice, to the space where the urethra and the vagina open (vaginal vestibulum). It may include a balloon at the tip to ensure retention within the gland. The device is typically used for drainage in the treatment of Bartholin's gland cysts and abscesses.

- Must be single use.
- Must be provided sterile.
- Must contain scalpel, syringe, needle, and inflatable catheter.

1.4.6.2. **Cervix Dilator:** a rod-like, solid surgical instrument designed to dilate the cervical canal after its insertion through the cervical os. Commonly known as a uterine dilator, it is typically made of metal or plastic material and has a tapered, rounded distal tip. It must have two different size diameters, one at each end of the instrument. The device is typically available in a set of graduated sizes that are applied in succession.

- Must have two different size diameters, one at each end of the instrument.

1.4.6.3. **Os Finder:** a rod like device used to find the cervix os (entry) a slim flexible body with a rounded tapered tip, widening to provide a small amount of dilation.

1.4.7. **Management of Miscarriage / Termination of Pregnancy:** includes, but not limited to products designed to capture and store pregnancy remains, manual vacuum aspiration devices.

1.4.7.1. **Capture of Pregnancy Remains**: to facilitate the sensitive handling and capture of pregnancy remains.

- Must be single patient use.

1.4.7.2. **Storage of Pregnancy Remains**: to facilitate the sensitive storage, and potential disposal of pregnancy remains.

- Must be single patient use.
- Must be opaque.

1.4.7.3. **Manual Vacuum Aspiration Device**: a manual, syringe-like device intended to be used in conjunction with an intrauterine cannula to aspirate fluid from the uterus for treatment of incomplete abortion, first trimester abortion, and/or for menstrual regulation; it may also be intended for endometrial biopsy. It includes a plunger with syringe barrel and appropriate connectors, seals, and valves, whereby fluid is intended to be aspirated directly into the barrel (i.e., not via a collection bottle).

- Must be provided sterile.

1.4.7.4. **Pre-Vacuum Lock:** Must have a method to create vacuum prior to curette / cannula insertion into the uterus.

1.4.7.5. **Post-Vacuum:** Must have a method to create vacuum once curette / cannula is in situ in the uterus.

1.4.8. **Vaginal Speculums**: used to open the walls of the vagina during gynaecological procedures. Includes, but not limited to Cusco, Collin, Sims, Fergusson. With or without smoke extractor. Available in reusable metal, single use metal and single use plastic types. The following are applicable to all vaginal speculum.

- We request a commitment from suppliers that the word ‘virgin’ will be eliminated from all packaging, literature, and catalogues (paper & online), and replaced with the description ‘extra small’.
- Must be available in a range of sizes.
- Cusco - Desirable for range to include sidewall retractors.

1.4.8.1. **Metal Vaginal Speculum Reusable**

- Must be suitable for sterilisation.
- Designed to be sterilised and reused on different patients.
- Packaging must indicate reusable

1.4.8.2. **Metal Vaginal Speculums Single Use**

- Packaging must indicate single use.
- Packaging must indicate if sterile or non-sterile.

1.4.8.3. **Plastic Vaginal Speculums Single Use**

- Packaging must indicate single use.
- Packaging must indicate if sterile or non-sterile.
- Desirable to have a TM-334 break test available should this be requested by a customer via NHS Supply Chain.
- Breakable speculums must have information pertaining to fail-safe break points in IFU.

1.5. **Period Products**

Products associated with managing or absorbing menstrual bleeding, post-partum bleeding and vaginal discharge.

- Must be provided with instructions for use written in English.
- Includes single use and single patient use products.
- Desirable to have sustainable products within the range

1.5.1. **Maternity Pads:** high absorbency pads specifically designed to absorb post-partum bleeding.

- Can be adhesive or non-adhesive.
- Can have wings or no wings.

1.5.2. **Menstrual Cup:** a cup-like receptacle placed by the user into the vagina to collect blood and cellular debris and discharges during menstruation and discharges outside of the monthly menses.

- Care and cleaning information must be provided in instructions for use.
- Instructions for use must contain information regarding use of the product in where the user has an intrauterine device in situ.
- Desirable to be provided in a range of sizes.

1.5.3. **Period Pads/Pant Liners**: absorbent pads designed to absorb menstrual fluid.

- Can be adhesive or non-adhesive.
- Can have wings or no wings.
- Desirable to have a range of sizes and absorbencies.

1.5.4. **Period Tampon**: a plug made of cellulosic or synthetic material that is inserted into the vagina to absorb menstrual blood or other vaginal discharge.

- Can be applicator or non-applicator.
- Desirable to have a range of sizes and absorbencies.
- Tampon packaging and instructional leaflets should comply with the UK Code of Practice for Tampon Manufacturers and Distributors (www.ahpma.co.uk/tampon_code_of_practice/) to ensure that users are provided with information about the risk of toxic shock syndrome (TSS), are aware of the symptoms of TSS and have guidance on the use of tampons to help minimise the risk.

1.5.5. **Period Sponge**: similar to period tampons but can be worn during sex, a synthetic, porous, absorbent device inserted into the vagina to absorb menstrual blood or other vaginal discharge.

- Desirable to have a range of sizes.
- Packaging and instructional leaflets should comply with the UK Code of Practice for Tampon Manufacturers and Distributors (www.ahpma.co.uk/tampon_code_of_practice/) to ensure that users are provided with information about the risk of toxic shock syndrome (TSS), are aware of the symptoms of TSS and have guidance on the use of tampons to help minimise the risk.

2. Lot 2

Lot 2 Sexual Health and Contraception. This lot includes products used in the prevention of sexually transmitted disease, contraception, topical preparation used in treatment and diagnosis as well as simple non pharmacological devices designed to improve sexual function		
Section	Products	Description
2.1	Condoms and physical barriers	Condoms and physical barriers includes personal protective devices designed to prevent the transmission of sexually transmitted disease and in the case of condoms prevent pregnancy. In addition it includes probe covers used to protect ultrasound devices during simple examinations as well as condom demonstrators and simple sexual health promotion materials
2.2	Contraception	Products include Intra uterine contracpetive devices (non hormonal), contraceptive diaphragms and associated consumables
2.3	Topical Preparations	Topical preparations are are applied as treatments for condomylata and granulomas or as lubrication to reduce friction during examinations, insertion of medical devices or during sexual intercourse
2.4	Mechanical Vibrators and Vaginal Therapy	This product group includes medical vibrators used for treatment of disorders such as premature ejaculation and vaginal therapy devices for management of vaginal stenosis, pelvic floor disorders and dyspareunia

2.1. **Condoms and Physical Barriers**

Personal protective devices designed to prevent the transmission of sexually transmitted disease and in the case of condoms prevent pregnancy. In addition it includes probe covers used to protect ultrasound devices during simple examinations as well as condom demonstrators and simple sexual health promotion materials.

Condoms, Dams and probe covers are manufactured from natural rubber latex or synthetic polymer. All products must be:

- Individually wrapped and suitable for STI protection and be smooth or without texture
- Products should be natural or neutral in colour unless flavoured
- All condoms must be prelubricated, without spermicide or additives to enhance stimulation such as cooling or warming.

2.1.1. **Internal condoms:** Also known as female condoms, an internal condom is a sheath typically with rings on either end to maintain stability in use. They are typically >60mm width

- May be manufactured from natural rubber latex or synthetic polymer.
- Must be supplied individually wrapped

Standards for Internal (Female) Condom	
ISO 25841:2017+A1:2020	Female condoms. Requirements and test methods.

2.1.2. **Penile Condoms – Latex:** Natural rubber latex (NRL) sheaths intended to completely cover the penis during coitus. Available in a range of styles and types. All types must be plain appearance (without ribs, dots, texture)

2.1.2.1. **Regular:**
Width 50-55mm
Maximum thickness 70 microns

2.1.2.2. **Delay:**
Must include additive to reduce sensation (including but not limited to anaesthetic agents)
Additive ingredients must be included on the product.

2.1.2.3. **Large:**
Minimum width 55mm
Maximum thickness 70 microns

2.1.2.4. **Extra Thick:**
Minimum thickness 90 microns

2.1.2.5. **Trim:**
Maximum width 50mm
Maximum thickness 70 microns

2.1.2.6. **Extra Thin:**
Maximum thickness 60 microns

2.1.2.7. **Flavoured:**
Width 50-55mm
Maximum thickness 70 microns
Must be supplied in mixed packs

Standards for Penile Natural Rubber Latex condoms	
ASTM D3492 - 16	Standard Specification for Rubber Contraceptives (Male Condoms)
BS EN ISO 4074:2015	Natural rubber latex male condoms. Requirements and test methods.
BS ISO 16038:2017	Male condoms. Guidance on the use of ISO 4074 and ISO 23409 in the quality management of condoms.
BS ISO 29943-1:2017	Condoms. Guidance on clinical studies. Male condoms, clinical function studies based on self-reports.
PD ISO/TR 19969:2018	Guidance on sample handling for determination of bursting volume and pressure, and testing for freedom from holes for male condom
BS ISO 29941:2010	Condoms. Determination of nitrosamines migrating from natural rubber latex condoms.

2.1.3. **Penile Condoms – Non Latex/Synthetic Polymer:** Synthetic polymer sheaths intended to completely cover the penis during coitus. Must be without flavour or texture such as ribbed/dotted

2.1.3.1. **Regular:**
Maximum width 54mm

2.1.3.2. **Large:**
Minimum width 55mm

Standards for Penile condoms - Non Latex	
ASTM D6324- 11(2017)	Standard Specification for Male Condoms Made from Polyurethane.
BS ISO 23409:2011	Male condoms. Requirements and test methods for condoms made from synthetic materials
PD ISO/TR 19969:2018	Guidance on sample handling for determination of bursting volume and pressure, and testing for freedom from holes for male condom
BS ISO 16038:2017	Male condoms. Guidance on the use of ISO 4074 and ISO 23409 in the quality management of condoms
BS ISO 29943-1:2017	Condoms. Guidance on clinical studies. Male condoms, clinical function studies based on self-reports

2.1.4. **Oral dams (prophylactic)**

A natural rubber latex or synthetic polymer sheet intended for use during oral-vaginal sexual activity to reduce transmission of transmission of sexually transmitted infection.

Standards for prophylactic dams	
BS ISO 29942:2011	Prophylactic dams, requirements and test methods

2.1.5. **Probe Covers – Latex:** A natural rubber latex sheath intended to be used as a physical barrier for protection against body fluids and/or to maintain the required hygienic level of an ultrasound imaging system transducer (probe) used in natural body orifices (e.g. vagina, rectum) during a simple diagnostic ultrasound examination. May be supplied sterile and non-sterile.

- Single use
- Sized to fit transducers: 0.8″ (2 cm), 1″ (2.5 cm) and 1.5″ (3.8 cm) in diameter.

2.1.6. **Probe Covers – Non Latex/Synthetic Polymer:** A synthetic polymer sheath intended to be used as a physical barrier for protection against body fluid and/or to maintain the required hygienic level of an ultrasound imaging system transducer (probe) used in natural body orifices (e.g., vagina, rectum) during a simple diagnostic ultrasound examination. May be supplied sterile and non-sterile.

- Single use
- Sized to fit transducers: 0.8″ (2 cm), 1″ (2.5 cm) and 1.5″ (3.8 cm) in diameter.

2.1.7. **Condom Demonstrators:** A model for teaching penile condom application technique.

- Must be made of a non-absorbent material.
- Must include instructions for cleaning.
- Similar appearance to a penis

2.1.8. **Sexual Health Promotion:** Items for promotion of sexual health services and condom use. May include key rings. Items including condoms must adhere to condoms standards as listed.

2.2. **Contraception**

2.2.1. **Intrauterine contraceptive device, metal covered (IUCD**): A contraceptive device intended to be introduced (non-surgically implanted) within the uterine cavity close to the fundus to prevent conception of pregnancy.

Products must be suitable for either 5 year or 10-year use and can be in a range of styles.

- Must contain a maximum 380mm2 copper.
- Must be supplied sterile.

Standards for IUCDs	
BS ISO 11249:2018 .	Copper-bearing intrauterine contraceptive devices. Guidance on the design, execution, analysis and interpretation of clinical studies.
BS EN ISO 7439:2023	Copper-bearing contraceptive intrauterine devices. Requirements and tests

2.2.2. **Contraceptive Diaphragm Pessary:** A circular device made of silicone that is placed in the vagina prior to intercourse to mechanically prevent conception**.**

- Must be single patient use.
- Must be provided with instructions for use written in English including cleaning and storage instructions. Instructions including pictures/infographic to demonstrate fitting are desirable.

Standards for contraceptive diaphragms	
ASTM D6976 - 13(2018)	Standard Specification for Rubber Contraceptives— Vaginal Diaphragms
BS ISO 8009:2014	Mechanical contraceptives. Reusable natural and silicone rubber contraceptive diaphragms. Requirements and tests.

2.2.3. **Contraception Accessories:** Used in the insertion, removal or management of IUCDs and contraceptive diaphragms. Including but not limited to insertion and removal devices, thread cutters and contraceptive gel.
Devices must be supplied sterile and individually packaged.
Contraceptive gels containing spermicide must be listed as medicines.

2.2.4. **Contraceptive gel:** suitable for use with a silicone diaphragm

- Must not contain spermicide.

2.2.5. **IUCD thread cutters:** manual bladed device used in gynaecological procedures to cut IUCD threads

- Minimum 190mm handle length

2.2.6. **IUCD thread retrievers:** Long thin device designed to be inserted into the vagina to capture IUCD threads to enable management of the device.

2.2.7. **IUCD removal device**: A hand held device with overlapping toothed end used to grasp IUCD threads and enable them to be held firmly to support removal of the device.

2.3. **Topical Preparations**

Products that are applied as topical treatments or as lubrication to reduce friction during examinations, insertion of medical devices or during sexual intercourse.

2.3.1. **Topical Treatments**

2.3.1.1. **Topical treatment for Condomylata**: A compound or solution intended to be topically applied to the surface of a wart. As an active ingredient it may include acid (e.g., formic acid) for drying warts, or plant extracts (e.g., oils, resins) for wart necrosis.

- Must include sufficient solution for multiple applications.
- Desirable to include narrow nozzle/fine tube for accurate application.
- Must have ingredients on product and /or packaging.
- Must have expiry date on product and packaging.

2.3.1.2. **Topical treatment for Granuloma:** used to treat umbilical granuloma A short, hand-held stick or pencil containing silver nitrate at the distal end, in solid form, intended to be applied to umbilical granuloma to cauterize skin for their removal and to facilitate skin re-epithelialization; or applied as a haemostatic agent

2.3.1.3. **Silver Nitrate:**

- Must be single patient use.
- Desirable to be available in a range of strengths.
- Disposal information must be provided in instruction for use.

2.3.2. **Lubricants:** Lubricants are provided in a range of types including those for general use in medical instrumentation and examination and sexual intercourse to reduce friction

2.3.2.1. **Sterile Lubricants:** Intended for use in a general body orifice to reduce friction and ease digital examination or instrumentation for diagnostic and therapeutic purposes

- Must be sterile
- Must be water soluble and suitable for 'in use of greater than 30 minutes' (Class IIb)
- Must have minimum viscosity of 10 000 centipose
- Individual sachets must have tear here/dotted lines visible to aid opening
- Non white coloured packaging desirable
- Carbomer free version desirable

2.3.2.2. **Non-Sterile Lubricants:** A non sterile lubricant substance intended to reduce friction and used to for digital examination or instrumentation for diagnostic purposes where a sterile product is not required

- Must be supplied with the ingredients listed.
- Must have minimum viscosity of 10 000 centipose.

- Must be water soluble and suitable for 'in use of greater than 30 minutes' (Class IIb)
- Individual sachets must have tear here/dotted lines visible to aid opening.

2.3.2.3. **Sexual Lubricants:** Lubricant substance intended to reduce friction during sexual intercourse which may be water based or non-water-based and non-sterile. All sexual lubricants must be available in sachets. Typically lighter/thinner than lubricant for instrumentation

- Must be water soluble and suitable 'in use' for greater than 30 minutes (Class IIb).
- May be flavoured.
- Must indicate compatibility with latex, silicone or other synthetic polymers used in sexual health devices such as condoms and diaphragms.

2.4. **Medical Vibrators and Vaginal Therapy**

Medical vibrators used for treatment of disorders such as premature ejaculation and vaginal therapy devices for management of vaginal stenosis, pelvic floor disorders and dyspareunia.

2.4.1. **Medical vibrator:** A vibration device applied to the penile head to desensitise and extend time to climax, used in the treatment of premature ejaculation.

- Must include instructions for use and disposal

2.4.2. **Vaginal Dilators:** A firm rod-like instrument designed to enlarge the vagina during examination, treatment, and/or during surgical procedures. It can also be inserted into the vagina and worn for prescribed periods to maintain vaginal patency after surgery (e.g., transgender vaginoplasty) or radiation treatments, or to stretch the vaginal orifice (the introitus) when it is unusually narrow due to a birth defect or vaginismus (the inability of the vaginal sphincter to relax). The device is typically available in a set of graduated sizes and the user is typically instructed to begin with the smallest diameter, increasing in size until satisfactory patency is achieved.

- Must be provided in a range of sizes.
- Desirable to be provided in kit form, for example a set of dilators +/- bag.

2.4.3. **Pelvic Floor Trainers:** a manual device used by women to provide Kegel exercise (alternate contraction and relaxation of perineal muscles) to treat urinary stress incontinence, sexual dysfunction, or to tone the muscles of the pelvic floor. It is available in a variety of designs that commonly includes a spring-loaded, split, cantilevered cylinder that requires the voluntary contraction of the vagina to squeeze it together, or a solid metal, profiled weight that is gripped by the vaginal muscles as gravity pulls it downward.

2.4.4. **Vaginal Trainers:** a non-sterile, hand-held, retractor-like device intended to be used to manually reduce a rectocele (herniation of lower bowel/rectum through a vaginal wall tear) during defecation to facilitate bowel emptying. It is intended to be used by direct application into the vagina by the patient during routine self-treatment to replace digital

reduction and as an alternative to the more permanent pessary or surgical repair. It is typically made of plastic material and can be reused after appropriate cleaning.

2.4.5. **Penetration Customisation Device:** a device which is worn at the base of the penis during sexual intercourse designed to tailor penetration depth.