**NON STANDARD SURGICAL THEATRE GOWN**

|  |  |
| --- | --- |
| **STANDARDS AND LEGISLATION** | |
| Non Standard surgical theatre gown | **BS EN 13795:2011+A1: 2013**  All products must have their CE marking clearly evident on the product and/or packaging and must conform to the relevant directive:  **Medical Devices Regulation 2017/745**    Any product that contains phthalates must be indicated on the packaging in accordance with:  **Medical Devices Regulation 2017/745.**  **Personal Protective Equipment Directive 89/686/EEC**  **BS EN 13795:2019 or equivalent standard**  Surgical drapes, gowns and clean air suits, used as medical devices for patients, clinical staff and equipment. General requirements for manufacturers, processors and products, test methods, performance requirements and performance levels.  **BS** **EN11810:2015.** Must be fire resistant/ tested for laser ignition and penetration |

**Standard gown specifications**

All gowns must comply with the following,

* Must be supplied sterile
* External packaging must state, single use, latex free, sterile, expiry date, reorder reference, and GS1 barcode compliant.
* Must be latex free
* Be anti-static
* Tie lengths on the inside of the gown must be between 35cm and 50cm (+/- 10%)
* Tie lengths on the outside of the gown must be between 35cm and 75cm (+/- 10%) to prevent them touching the floor when being worn.
* In addition the products will need to be CE marked
* Must be individually packaged with a sterile sheet inside at least 50cm by 50cm wrapped around the gown and towels to enable sterile opening.
* Must be presented to enable correct donning of the gown and the towels placed on top.
* Packaging must indicate size of the gown with length in cms from neck to bottom of front and an image representing the gown and length.
* Type of gown “Standard” must be clear on the external packaging.
* Sizing to be in line with EN13402
* Must be low linting ≤3.5 as per EN 9073-10 as per below
* Tear resistance must be in line with EN29073-3 and between MD >50N CD >30N as per below

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **EN 20811 Hydrostatic pressure in all areas** | **EN 29073-3  Tear resistance** | **EN13795 MUST PASS** | **Linting  ISO 9073-10** | **Towels x2** | **Towel Absorbency** |
| 50cm H₂O | MD >50N CD >30N | Pass | <3.5 LPM | 30x40cm | Able to dry hands to above the elbow |
| 50cm H₂O | MD >50N CD >30N | Pass | <3.5 LPM | 30x40cm | Able to dry hands to above the elbow |
| 50cm H₂O | MD >50N CD >30N | Pass | <3.5 LPM | 30x40cm | Able to dry hands to above the elbow |
| 50cm H₂O | MD >50N CD >30N | Pass | <3.5 LPM | 30x40cm | Able to dry hands to above the elbow |
| 50cm H₂O | MD >50N CD >30N | Pass | <3.5 LPM | 30x40cm | Able to dry hands to above the elbow |
| 50cm H₂O | MD >50N CD >30N | Pass | <3.5 LPM | 30x40cm | Able to dry hands to above the elbow |
| 50cm H₂O | MD >50N CD >30N | Pass | <3.5 LPM | 30x40cm | Able to dry hands to above the elbow |
| 50cm H₂O | MD >50N CD >30N | Pass | <3.5 LPM | 30x40cm | Able to dry hands to above the elbow |
|  |  |  |  |  |  |

* Must not have any element that may fall off while in use, for example labels, toggles or branding tabs.
* All gowns that fasten using hook and loop fasteners, must be positioned to prevent irritation for the wearer and at least 6cm long of both strips.
* Provide the full range of gown lengths from 105cm through to 160cm and the relevant arm, chest, neck sizes as per below.

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Suppliers size description** | **Gown Length** | **Chest** | **Arm length to cuff** | **Cuff length** | **Neck diameter** | **Internal belt x2** | **External belt with card** | **External belt without card** |
| Small | 105-110cm | 110-120cm | 55-60cm | 7-9cm | 55-65cm | 35-40cm | 65-70cm | 35-40cm |
| Medium | 111-120cm | 120-130cm | 53-60cm | 7-9cm | 55-65cm | 35-40cm | 65-70cm | 35-40cm |
| Large | 121-130cm | 140-150cm | 55-60cm | 7-9cm | 65-70cm | 38-45cm | 65-70cm | 37-45cm |
| Large Long | 140-145cm | 140-150cm | 55-60cm | 7-9cm | 65-70cm | 38-45cm | 65-70cm | 37-45cm |
| Extra Large | 130-140cm | 160-170cm | 61-65cm | 7-9cm | 70-75cm | 38-45cm | 70-75cm | 45-55cm |
| Extra Large Long | 150-155cm | 160-170cm | 61-65cm | 7-9cm | 70-75cm | 38-45cm | 70-75cm | 45-55cm |
| Extra Extra Large | 130-140cm | 180-190cm | 65-70cm | 7-9cm | 70-75cm | 38-45cm | 70-75cm | 50-55cm |
| Extra Extra Large Long | 150-160cm | 180-190cm | 65-70cm | 7-9cm | 70-75cm | 38-45cm | 70-75cm | 50-55cm |

* In accordance with the Control of Substances Hazardous to Health Regulations 2002 (as amended) safety data sheets for all products that fall under this Regulation must be provided to NHS Supply Chain.
* All products and packaging should be **latex free** where possible. Any products or packaging containing latex must be clearly labelled as such to inform the user.
* All products must be supplied with a minimum 3 years shelf life from the date of manufacture.
* Where applicable all products must be supplied with instructions for use and disposal/recycling instructions or symbols printed in English.
* This specification is for sterile single use surgical gowns used to cover the wearer whilst in an operating theatre or environment which requires a sterile covering in such a way as to prevent exposure to potentially contaminated fluids, including those which may contain pathogens as well as helping to prevent the wearer from contaminating the clean surgical site.
* Products include:

Sterile single use Standard Gown

Sterile Single use Standard High-Performance gown

Sterile Single use Zonal Reinforced Gown

Sterile Single use Zonal Impervious Gown

Single Use, Sterile Fully Impervious Gown

|  |  |  |
| --- | --- | --- |
| **Type of gown** | **Hydrostatic pressure** | **Guidance for use** |
| Standard | >50cm H20 | Minimal exposure to fluids |
| Standard High performance | >100cm H20 | Potential risk of low levels of fluids for a limited period in all areas |
| Zonal reinforced | >125cm H20 (Critical areas) | Potential contact of high- risk items with the gown in zonal areas |
| Zonal Impervious | >200cm H20 (Critical areas) | Potential risk of high levels of fluids in zonal areas for prolonged lengths of time |
| Fully Impervious | >200cm H20 | Potential risk of high levels of fluids in all areas |

|  |  |  |  |
| --- | --- | --- | --- |
| Date | Author | Reference | Version |
| 19th March 2020 | AL / JT | SCCLGOWNS/305 | 1.0 |