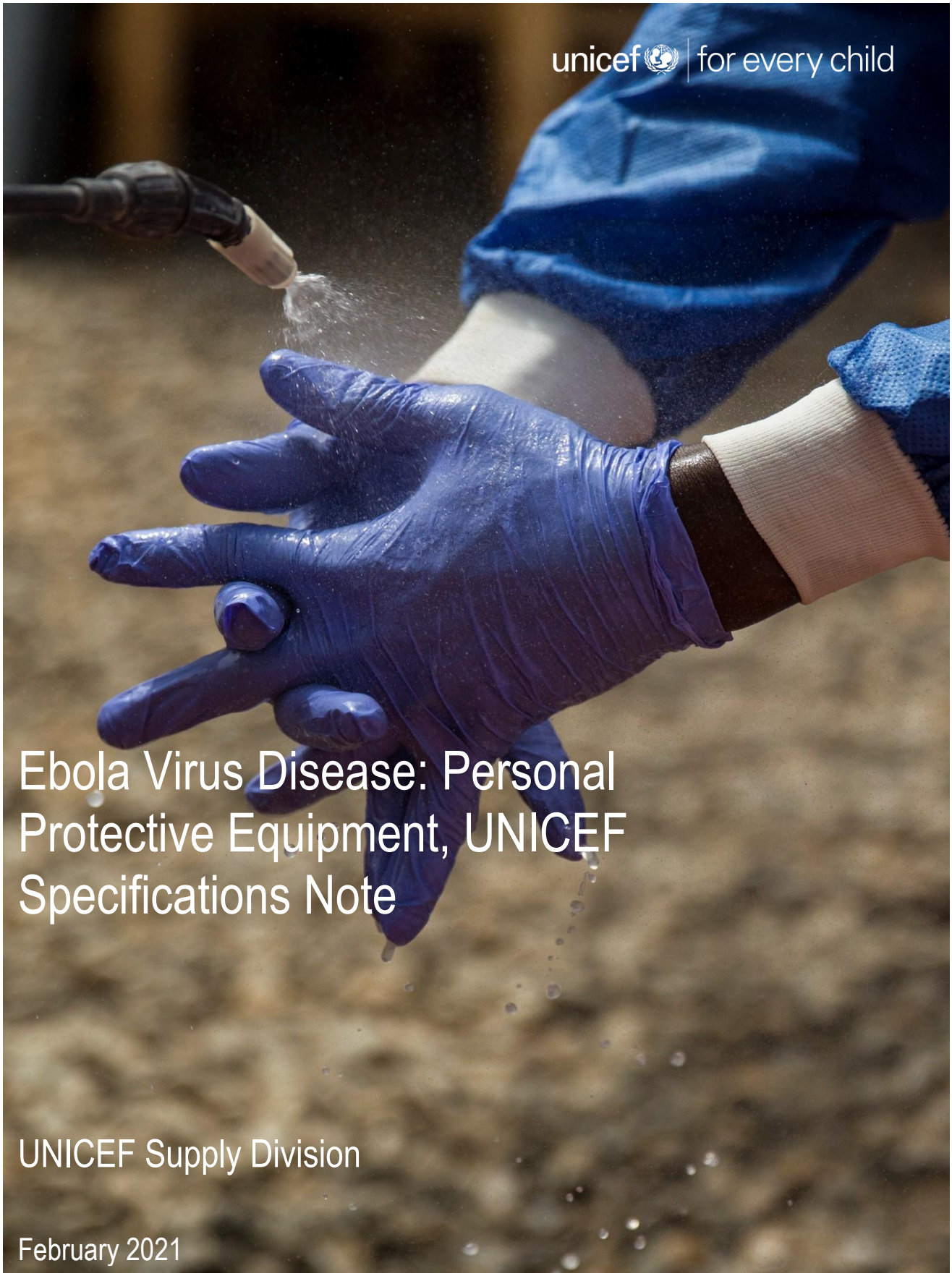

Ebola Virus Disease: Personal Protective Equipment, UNICEF Specifications Note

UNICEF Supply Division

February 2021

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1. Background

The recent outbreaks of life-threatening infections and re-emerging infectious diseases highlight the need for prevention, preparedness, as well as effective emergency response and infection control, notably in public health care facilities for frontline workers, and patients.[1] They highlight the need for global preparedness to ensure an efficient and effective rapid response to health emergencies. Any rapid response to an acute public health emergency requires an initial risk assessment to ensure defensible decision-making, including the implementation of appropriate control measures. A systematic approach to a public health risk assessment can provide the basis to prioritise actions to alleviate the consequences on affected populations.

UNICEF identified several diseases, including Ebola virus disease (EVD) for which it is making organizational preparations and support packages. They include disease-specific technical guidance documents, pre-positioned stock, and supply requirements. Personal protective equipment (PPE) is a key component in the response to outbreaks from emerging pathogens specially in the absence of effective medial counter measures (MCM). The equipment needs to be designed according to certain specifications and meet specific standards to ensure the level of safety needed for frontline workers during their care of patients with infectious diseases.

This note summarizes the specifications and the standards for these PPEs that are part of the supplies UNICEF makes available for Ebola preparedness and response.

2. Personal Protective Equipment

The frontline workers engaged in outbreak response are amongst those most exposed to an elevated level of high-risk. In order to break the transmission of EVD between frontline workers and their surrounding working environment, adherence to strict infection prevention and control procedures is mandatory. In addition to the firm application of standard, droplets and contact precautions, all PPEs supplied to those areas must be adequate and effective in protecting frontline workers from infection; provide a maximum safety level against infective agents; and be used in accordance with instructions.

Global response and recommendations as per the "right" PPE standards to be used in the safe management of EVD have been harmonised. The selection of appropriate PPE should be based on a hazard risk assessment and the case management activities in frontline areas, including patient care centres and burial sites.

Personal protective equipment refers to the different extended biological protection barriers used in combination to prevent both percutaneous and mucocutaneous exposure to EVD during the provision of medical and supportive care; or when coming in contact with EVD suspected or confirmed individuals. It includes barriers for head, nose, mouth, eyes, hands, and feet, as well as full body protection. All PPEs must be fluid-resistant, impermeable, and protect against contamination from all body fluids, including blood, or viral contaminated patient-used equipment. In selecting the right PPE specifications for frontline workers, the degree of contact with infectious material, and the potential for infected fluid penetration, should be considered.

In response to the risks highlighted above, UNICEF has identified, and has available PPE supplies according to the technical specifications as listed below. For more detailed information on UNICEF PPE supplies, please refer to UNICEF's Ebola: Health Emergency Supply Note.[2] The supply note provides an updated list of available supplies for the prevention, detection, and emergency response to any outbreak of EVD. It lists supplies for infection prevention and control (IPC) including PPE for standard and contact precautions against viral haemorrhagic disease, medical clothing and specific disinfectants; temperature monitoring devices; laboratory testing (EVD diagnostics); and waste management. It also makes provisions for medical and supportive care for suspected or confirmed individuals. The note also provides details on how UNICEF country

[1] Frontline workers: Burial teams, healthcare workers, water and sanitation officers, cleaners, amongst many others…
[2] UNICEF, *Ebola: Health Emergency Supply Note*, UNICEF, Copenhagen, February 2021.

offices, governments, and partners can procure emergency supplies through UNICEF as well as the vaccine through the International Coordination Group (ICG).

UNICEF provides (Table 1) the list of PPEs that are available for use in outbreak response to EVD via UNICEF's online Supply Catalogue, and for which it provides further detailed specifications and selection rational for each item below. It excludes the items for IPC used for general best practice, such as surgical cap, tunics, trousers and the biohazard bag.

Table 1 Ebola PPE List through UNICEF

Intervention	Area	Item Description	Material Number	Unit
Prevention and Control	IPC and PPE	Faceshield, fog-resistant, full face, disp.	S0305116	Each
		Goggles, protective, indirect side-ventil.	S0305144	Each
		Mask, high-fil, FFP2/N95/KN95, no valve	S0305153	Each
		Mask, high-fil, FFP2/N95/KN95, no valve/PAC-50	S0305156	Box
		Mask, surgical, type IIR, ties trap, disp./PAC-50	S0305135	Pack
		*Cap, surgical, bouffant, non-woven	S0305078	Each
		Hood, protection, Cat III	S0305124	Each
		Apron, protect, plastic, disp./PAC-100	S0305131	pack
		Apron, protect, plastic, reusable	S0305132	Each
		Coverall, protection, Cat III, type 3b, XL	S0305102	Each
		Coverall, protection, Cat III, type 3b, L	S0305103	Each
		Coverall, protection, Cat III, type 3b, M	S0305101	Each
		Gloves, heavy-duty, rubber/nitrile, pair, L	S0327552	Pair
		Gloves, heavy-duty, rubber/nitrile, pair, M	S0327551	Pair
		Gloves, heavy-duty, rubber/nitrile, pair, S	S0327550	Pair
		Gloves, w/o powder, nitrile, L, disp./BOX-100	S0969026	Box
		Gloves, w/o powder, nitrile, M, disp./BOX-100	S0969025	Box
		Gown, surgical, non-sterile, non-woven, disp, L	S0305138	Each
		Gown, surgical, non-sterile, non-woven, disp, XL	S0305140	Each
		Boots, rubber/PVC, reusable, pair, size 42	S0305061	Pair
		Boots, rubber/PVC, reusable, pair, size 43	S0305062	Pair
		Boots, rubber/PVC, reusable, pair, size 44	S0305063	Pair
		Boot cover, antiskid, elasticated, pair	S0305147	Pair
		Body bag, infection control, adult	S0990002	Each
		Body bag, infection control, child	S0990003	Each
		*Bag, biohazard, red, 100l/BOX-100	S0969007	Box
		*Trousers, surgical, woven, size L	S0305081	Each
		*Trousers, surgical, woven, size M	S0305080	Each
		*Trousers, surgical, woven, size XL	S0305082	Each
		*Tunic, surgical, woven, size L	S0305084	Each
		*Tunic, surgical, woven, size M	S0305083	Each
		*Tunic, surgical, woven, size XL	S0305085	Each

Source: UNICEF Supply Division

Note *: Item used for best practice, such as surgical cap, tunics, trousers and the biohazard bag are excluded from the details below on specifications.

SELECTION RATIONALE AND SPECIFICATIONS

3. BODY PROTECTION

3.1. Coveralls in high-risk settings

3.1.1. Selection rationale

In accordance with the European Union Regulation (EU) 2016 /425, biological protective coveralls fall under Category III: Chemical Protection Coveralls. The selection of coveralls is based on garment fabric, seam treatment and fabric/garment performance testing against specific norms.

Chemical protective coveralls certified to a specific type have different performance classes in terms of protection, durability, and comfort. As part of the EVD PPE, the appropriate selected protective coveralls should provide the following:

- High impermeability to liquid: Type 3 (liquid-tight) conforming to EN 14605:2005 are the appropriate coveralls providing higher protection against liquid penetration. In addition, the coveralls' seams are stitched and taped to provide the same level of liquid impermeability as the fabric.
- Impermeability to blood: Conforming to EN 14126:2003. The fabric used in manufacturing coveralls has to pass International Standard Organization (ISO)[3] standard ISO 16603:2004: laboratory test methods used to measure penetration resistance by blood and body fluids using synthetic blood. Six performance classes exist of which one is the lowest and six is the highest.
- Fabric material tested against viral penetration: Conforming to EN 14126:2003. The fabric used in manufacturing coveralls has to pass ISO 16604:2004: laboratory test methods used to measure penetration resistance by blood-borne pathogens using bacteriophage Phi-X-174. Six performance classes exist of which one is the lowest and six is the highest.

Table 2 UNICEF Accepted Performance Classes for Infective Agent Testing Standards and Coveralls Class Type

EN 14126: Performance requirements and test methods for protective clothing against infective agents	Coveralls protection Type
	Type 3 Coveralls
ISO 16603: Screening pressure test: Resistance to penetration by blood and body fluids using synthetic blood.	Class 3
ISO 16604: Resistance penetration by blood-borne pathogens using a bacteriophage Phi-X-174.	Class 2

Source: European Committee on Standardization / International Standardization Organization.

There are possible unknown risks that could build up on the coveralls during the provision of medical/cleaning services and activities in patient isolation areas located within EVD centres. EVD is classified as Risk Group 3 as per the EU Directive 2000/54/EC (protection of workers from risk related exposure to biological agents at work). Accordingly, UNICEF has specifically solicited the above ISO standard ISO 16604:2004 as the most critical standard in selecting coveralls to provide protection against viral transmission in the case of EVD. Only coveralls passing this ISO with a minimum performance class 2 are considered suitable for use in high-risk areas.

3.1.2. Coveralls

The list of coveralls below is sourced and supplied through UNICEF and provides products and options that meet the highest standard of protection.

UNICEF material numbers, product range.

- S0305101: Coverall, protection, Cat III, Type 3b, M
- S0305102: Coverall, protection, Cat III, Type 3b, XL
- S0305103: Coverall, protection, Cat III, Type 3b, L

UNICEF specifications

Disposable, single use liquid-penetration resistant, biohazard-protective coveralls with hood. For use in EVD patient-isolation units suitable for stringent infection prevention and control practices and tested against viral penetration. Protective seams provide a barrier equal to the fabric. Conforms to PPE (EU) 2016/425, Category III: Chemical protective coveralls, Type 3b and complies with EN 14605:2005+A1:2009 (or equivalent) marketing approval certificate. Complies with EN 14126:2003, passing infectious agent test according to ISO 16604:2004 standard at a minimum exposure to a pressure of 1.75kPa class 2 (or equivalent international standard). Available in various sizes: M, L, XL.

3.2. Surgical Gown in low-risk settings

For use in lower-risk areas such as triage centres, clinical care, or other lower-risk areas in health centre facilities.

UNICEF material numbers, product range.

- S0305138: Gown, surgical, non-sterile, non-woven, disposable, L
- S0305140: Gown, surgical, non-sterile, non-woven, disposable, XL

[3] International Organization Standard, *Standards*, ISO, Geneva, February 2020.

UNICEF specifications

Surgical gown with long sleeves and a waist tie that binds at the side or back. Non-woven material, liquid penetration resistant in critical areas (chest and sleeves). Size approximately 150 cm x 130 cm (W x L). Single use, disposable. Conforms to EU Medical Devices Directive 93/42/EEC, Class I and EN 13795 standard performance (SP) or high performance (HP), (or equivalent standard)

4. HAND PROTECTION

4.2. Examination gloves

UNICEF material numbers, product range.

- S0969021: Gloves, w/o powder, nitrile, S, disposable, BOX-100
- S0969025: Gloves, w/o powder, nitrile, M, disposable, BOX-100
- S0969026: Gloves, w/o powder, nitrile, L, disposable, BOX-100

UNICEF specifications

Disposable, ambidextrous, non-sterile, single-use, nitrile examination gloves with a thickness at fingertips of ≥ 0.08 mm, conforms to PPE regulation (EU) 2016/425, Category III and EN 374 standard (gloves giving protection from chemicals and micro-organisms plus Medical Device Directive 93/42/EEC and EN 455 standard. Available in various sizes: S, M and L.

4.3. Heavy-duty gloves

UNICEF material numbers, product range.

- S0327550: Gloves, heavy-duty, rubber/nitrile, S
- S0327551: Gloves, heavy-duty, rubber/nitrile, M
- S0327552: Gloves, heavy-duty, rubber/nitrile, L

UNICEF specifications

Nitrile: minimum length 32-38 cm. Left/right pair. Knitted inner lining to facilitate slide-in and removal. Thickness at fingertips: ≥ 380 um. Cleanable with water and disinfectant (resisting both ethanol solutions 70% and chlorine solutions >0.5%). Heavy-duty, conforms to PPE regulation (EU) 2016/425, Category III: EN 374-1, 2, 4 and 5, as well as EN 420 and EN 388 (high cracking, puncture, and abrasion resistant, levels: ≥ 4-1-0-1) (or equivalent standards). Available in sizes: S, M, and L.

5. FOOT PROTECTION

5.2. Boots

UNICEF material numbers, product range.

- S0305061: Boots, rubber/PVC, reusable, pair, size 42
- S0305062: Boots, rubber/PVC, reusable, pair, size 43
- S0305063: Boots, rubber/PVC, reusable, pair, size 44

UNICEF specifications

Rubber or polyvinyl chloride (PVC), no steel reinforcement, ,slide-in and removal insole. Waterproof, oil-resistant, acid and alkali resistant, anti-slip, puncture and abrasion resistant.

5.3. Boot covers

UNICEF material number, product range.

- S0305147, Boot cover, antiskid, elasticated, pair

UNICEF specifications

High quality heavy duty over boot cover, puncture and abrasion resistant. Entirely liquid impermeable and repellent (adequate protection against bio-hazardous liquids).

6. EYE PROTECTION

6.2. Goggles

UNICEF material number, product range.

- S0305144: Goggles, protective, indirect-side-ventilation

UNICEF specifications

Plastic wrap-around safety goggles with indirect ventilation, preferably on the side with wide viewing angle, translucent frame and broad strap to increase comfort for long time wear. Anti-fog treatment. Conforms to the American National Standards Institute (ANSI) ANSI Z87.1-2010 standard (or equivalent standard).

6.3. Face shield, reusable and single use

UNICEF Material Number, Product Range.

- S0305116: Faceshield, fog-resistant, full face, disposable

UNICEF specifications

Clear polycarbonate shield, thickness approx. 0.3 mm. Full face-length from headband down by approximately 30 cm. Adjustable headband, designed for comfort in tropic climate. Shield is anti-fog treated/coated. Conforms to EN 166 (or equivalent standard).

7. NOSE AND MOUTH PROTECTION

7.2. Respirators

UNICEF material number, product range.

- S0305153: Mask, high filtration, FFP2/N95/KN95, no valve
- S0305156: Mask, high filtration, FFP2/N95/KN95, no valve, PAC-50

UNICEF specifications

Disposable, none-valve respirators. Filtration level: > 95 % for particles from 0.1 to 0.3 micron. Air permeability: > 2 mm H2O. Without valve. Malleable nose-bridge. Two pre-attached elasticated straps, fitting (i) around top of the head, (ii) around base of the head. Respirator mask conforms to standards US Standard Centres for Disease Control nd Prevention (CDC) National Institute for Occupational Safety and Health (NIOSH) NIOSH N95 or PPE regulation (EU) 2016/425, category III: EN 149:2001/FFP2 or Chinese National Standards (CNS) GB 2626, minimum KN95.

7.3. Surgical mask type IIR

UNICEF material number, product range.

- S0305135: Mask, surgical, type IIR, tie strap, disposable, PAC-50

UNICEF specifications

Splash resistant, type IIR surgical mask. Bacterial filtering efficiency: equal to or greater than 98%. Breathing resistance: equal to or less than 49 Pa/cm^2. Splash resistance pressure: greater than 120 mmHg. Comprised of 3 or 4 non-woven layers and malleable nose-bridge. Conforms to EU Medical Devices Directive 93/42/EEC, Class I and EN 14683 standard for type IIR (or equivalent international standard).

8. BODY PROTECTION

Plastic apron to be worn over the coveralls or gown as a first soiled layer. It does not protect total body area but adds additional protection. Depending on the procedure, it can repel excess fluid, particularly during activities related to washing, cleaning and handling bodies / cadavers.

8.2. Heavy-duty apron

UNICEF material number, product range.

- S0305132: Apron, protection, plastic, reusable

UNICEF specifications

Reusable straight, sleeveless, protective apron with adjustable back- and neckband. Seamless liquid proof and stain resistant. Both back- and neckband can be adjusted/fastened allowing for easy donning and doffing. Material: durable environmentally friendly plastic. Size approximately: 120 cm x 150 cm (W x L). Thickness, approximately: 300um. Cleanable with water and disinfectant (ethanol 70% and chlorine solution 0.5%).

8.3. Disposable apron

UNICEF material number, product range.

- S0305131: HE* Apron, protection, plastic, disposable, PAC-100

UNICEF specifications

Single use, sleeveless apron with adjustable back- and neckband. Seamless, liquid proof and stain resistant. Material: durable environmentally friendly plastic, polyethylene (PE). Size, approximately: 85 cm x 130 cm (W x L). Thickness: approximately 50µ.

9. HEAD PROTECTION

9.2. Hood with or without integrated mask

UNICEF material number, product range.

- S0305124: Hood, protection, Cat III

UNICEF specifications

Disposable, single use, liquid-penetration resistant, biohazard-protective hood for use in EVD patient-isolation units suitable for infection prevention and control practices. Tested against microbial penetration. Hood covering full neck and parts of shoulders. Conforms to European Regulation (EU) 2016/425 on personal protective equipment Category III: Chemical protective coveralls, Type 3 comply with EN14605:2005+A1:2009 (or equivalent standard) marketing approval certificate. Barrier to infective agent standards: EN 14126:2003 certified passing infectious agent test according to ISO 16604:2004 (Resistance to penetration by blood-borne pathogens using bacteriophage Phi-X 174) standard at minimum exposure pressure of 1.75kPa class 2 (or equivalent international standard), (EU) 2016/425 (or equivalent international standard).

10. BIOHAZARD CONTAINEMENT

10.2. Body bag - adult size

UNICEF material number, product range.

- S0990002 Body bag, infection control, adult

UNICEF specifications

Body bag with absorbent pad used for packing and transporting contagious human corpses. Adult size. Tear proof and puncture resistant. 100% leak proof seams. Seams entirely heat-sealed, width minimum 5 mm. Material: PEVA/ Vinyl / or other suitable material. Special linear reinforced material. Chloride and carbon free. Buried in soil, the body bag will remain solid over a period of minimum 5 years. Thickness: 300 to 400 microns (um). Colour: white. Carry capacity: min. 120 kg. Minimum of 6 padded carry handles reinforced and integrated into the bag material. Dimensions, unfolded, approximately: 230 cm x 100 cm (L x W). Dimensions, folded, approximately: 45 cm x 35 cm (L x W). Zipper: High quality black or white zipper, smooth running with teeth made of nylon. Full-length U- or J-shaped zipper, with double runner zipper is sewed into the body bag fabric with double stitch. Large plastic or sturdy cloth loops, on each of the zipper runners. With 25 cm return allowing to show the face of the decease person. Absorbent pad: for body bags to absorb fluids. Integrated and prefixed inside of the body bag, with water-resistant double-sided tape. Size: 160 cm x 70 cm (± 15%) Absorbent pad material: Thick

cotton lining on polyethylene base. Preferably absorbent on both sides. Two layers of padding. Absorption capacity: minimum 5 litres. Resistant to 0.5% chlorine solution. Integrated transparent label pouch 10 cm x 15 cm (L x W) for placement of identification tag. Single use and disposable. Shelf life: minimum 5 years. Conforms to US Department of Labor Occupational Safety and Health Administration (OSHA) regulation 3130 for Universal Precautions involving containment of body fluids and protection from blood borne pathogens or eEquivalent applicable product or other performance standard(s).

10.3. Body bag - child size

UNICEF material number, product range.

- S0990003 Body bags, infection control, child

UNICEF specifications

Body bag with absorbent pad used for packing and transporting contagious human corpses. Child size. Tear proof and puncture resistant. 100% leak proof seams. Seams entirely heat-sealed, width minimum 5 mm. Material: PEVA/ Vinyl / or other suitable material. Special linear reinforced material. Chloride and carbon free. Buried in soil, the body bag will remain solid over a period of minimum 5 years. Thickness: 300 to 400 microns (um). Colour: white. Carry capacity: min 90 kg. Minimum of 6 padded carry handles reinforced and integrated into the bag material. Dimensions, unfolded, approximately: 150 cm x 100 cm (W x L). Dimensions, folded, approximately: 45 x 35 cm (L x W). Zipper: high quality black or white zipper, smooth running with teeth made of nylon. Full-length U- or J-shaped zipper, with double runner Zipper is sewed into the body bag fabric with double stitch. Large plastic or sturdy cloth loops, on each of the zipper runners. With 25 cm return allowing to show the face of the decease person. Absorbent pad: for body bags to absorb fluids. Integrated and prefixed inside of the body bag, with water-resistant double-sided tape. Approx. size: 130 cm x 70 cm (± 15%) Absorbent pad material: Thick cotton lining on polyethylene base. Preferably absorbent on both sides. Two layers of padding. Absorption capacity: minimum 5 litres. Resistant to 0.5% chlorine solution. Integrated transparent label pouch 10 cm x 15 cm (L x W) for placement of identification tag. Single use and disposable. Shelf life: minimum 5 years. Conforms to OSHA regulation 3130 for Universal Precautions involving containment of body fluids and protection from blood borne pathogens or equivalent applicable product or other performance standard(s).

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