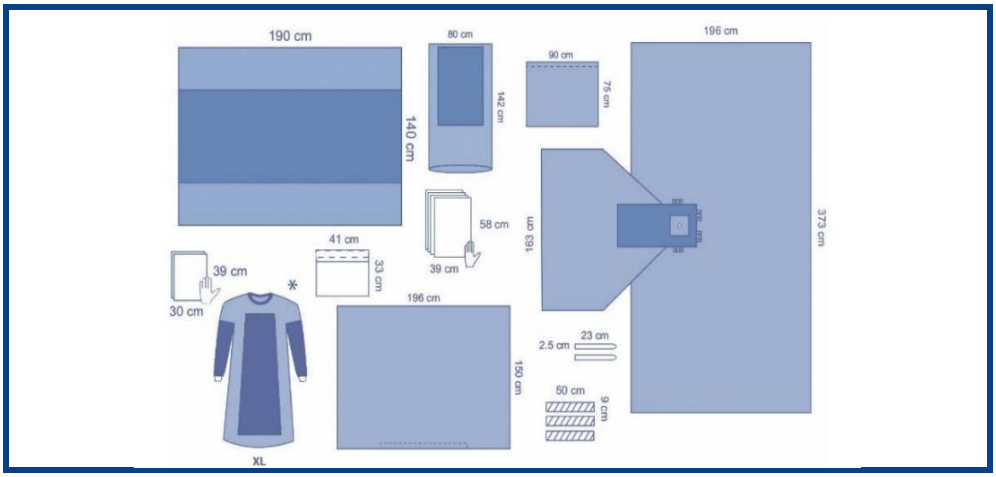
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Technical Sheet

OPS™ Ultimate

Extremity pack

Reference(s)	**CPU29022CE**
Description	A SMS wrap 90x90 cm contains: A back table cover, 140x190 cm, 50 µm*, containing: - 1 SMS ste back gown, with poly reinforcement, hook and loop adjustable neck, XL, 140 cm with PPE/MD sticker** - 1 mayo stand cover, 80x142 cm, 55x88 cm reinforcement* - 4 absorbent towels, 58x39 cm unfolded - 1 bi-laminate adhesive drape, 90x75 cm* - 1 bi-laminate drape 196x150 cm, 98 cm adhesive* - 1 clear plastic instrument pouch, 33x41 cm, adhesive - 2 hook and loop tube holders 2.5x23 cm - 3 adhesive tapes, 9x50 cm - 1 tri-laminate hand drape, 196x373 cm, 43x86 cm reinforcement, 3 cm diameter elastic fenestration, 4 cord holding tabs, with table extension*
Main materials	Absorbent and impervious tri-laminated material (polyethylene + polypropylene) HSPP absorbent reinforcement (polypropylene + polyethylene) Absorbent and impervious bi-laminated material (polyethylene + polypropylene) Gowns : SMS (polypropylene) PE reinforced
Pack factor	4 unit per case
Packaging	Sterilization bag 1 polyliner contains all the units in a carton box
Legal Manufacturer	Medline International France SAS In compliance with EN ISO 13485
Regulation	The Extremity pack is in compliance with Medical Devices Regulation 2017/745 and UK MDR MD Class: I sterile *HP per EN13795-1 **HP: per EN13795-1 in reinforced areas **The Surgical gown is also in compliance with Personal Protective Equipment regulation 2016/425 - PPE category: III sterile CE 2797 MD class I sterile under regulation 2017/745 PPE category III under Regulation (EU) 2016/425 Certified by BSI Group The Netherlands B.V. 1066 EP, Amsterdam, Netherlands

•Please refer to complete labeling before using the product.

Retention period: End of life and support period

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**PPE Performances of the gown



EN 14605:
2005+A1:2009
Type PB[4]

Performance requirements (only on reinforced areas):

Test method	Performance level according to EN 14605: 2005+A1:2009
Abrasion	Class 1
Flex cracking	Class 6
Trapezoidal tear	Class 2/1
Tensile strength	Class 2/1
Puncture resistance	Class 2
Seam strength	Class 2

EN 374-3:2003 Resistance to permeation of chemicals:

Chemical	Material
Sulphuric Acid 96%	Level 1

Other information



EN 14126:2003
Type PB[4]-B

Test standard	Test method	Property	Performance level
EN 14126 (2003) + AC (2004)	ISO 16603 (2004)	Resistance to penetration by blood and body fluids	Class 3
EN 14126 (2003) + AC (2004)	ISO 16604 (2004)	Resistance to penetration by blood borne pathogens – Test method using Phi-X174 bacteriophage	Class 3
EN 14126 (2003) + AC (2004)	ISO 22610 (2006)	Resistance to wet microbial penetration	Class 6
EN 14126 (2003) + AC (2004)	ISO/DIS 22611 (2003)	Resistance to liquid aerosol penetration	Class 3
EN 14126 (2003) + AC (2004)	ISO 22612 (2005)	Resistance to dry microbial penetration	Class 3

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