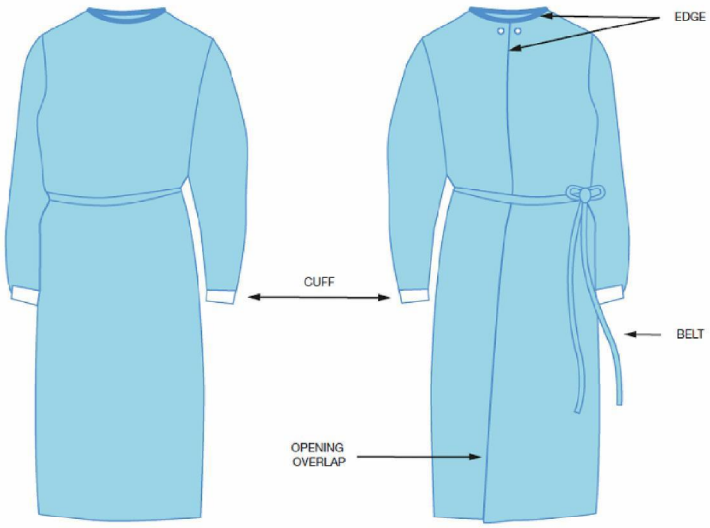
Technical sheet Isolation Gowns (disposable) **07-05-2020**

The (disposable) isolation gown is a non-sterile gown to provide moderate barrier to patients' body fluids and secretions. It is mainly used for patient treatment and epidemic prevention inspection in public places.
Gowns are cut wider through the chest and sleeves to be roomier . The soft and water-proofed fabric features advanced material technology provides a splash resistant barrier. It keeps comfortable while working, helping to feel confident and in control.



Tekening ter indicatie en om aan te geven welke onderdelen van belang zijn. Afkomstig uit een document van Klopman International (Italiaanse stoffenfabrikant)

Property		Inspection
Fit	Length: The gown should end between knees and ankles. Indicative for a size L this means a length of 120-125 cm from highest point shoulder.	Visual
	Cuffs: sleeves should end with cuffs or elastic band to fit in the gloves.	Visual
	Closure: the gown should close properly. In the neck with a Velcro or two bowed straps. A belt around the waist.	Visual
Fabric	Preferably PP SMS but alternative qualities are possible as long as they meet the qualifications as below.	Technical fabric sheet
	ISO 13795-1 : requirement standard performance, critical product area	Certificate
	Alternative AAMI PB70:2012 level 3	Certificate
Color	Blue or yellow. White in exceptional cases (urgency) and preferably with recognizable marking, to make it distinctive of the regular clothing.	Visual

Process	According to EN-ISO 13485	Certificate

Specifications ISO 13795-1

Table 1 — Characteristics to be evaluated and performance requirements for surgical gowns

Characteristic	Test method (for normative references see Clause 2)	Unit	Requirement			
			Standard performance		High performance	
			Critical product area	Less critical product area	Critical product area	Less critical product area
Microbial penetration — Dry	EN ISO 22612	CFU	Not required	≤ 300 [a]	Not required	≤ 300 [a]
Microbial penetration — Wet	EN ISO 22610	I_B	≥ 2,8 [b]	Not required	6,0 [b c]	Not required
Cleanliness microbial / Bioburden	EN ISO 11737-1	CFU/ 100 cm^2	≤ 300	≤ 300	≤ 300	≤ 300
Particle release	EN ISO 9073-10	$\log_{10}$ (lint count)	≤ 4,0	≤ 4,0	≤ 4,0	≤ 4,0
Liquid penetration	EN ISO 811	cm H_2O	≥ 20	≥ 10	≥ 100	≥ 10
Bursting strength — Dry	EN ISO 13938-1	kPa	≥ 40	≥ 40	≥ 40	≥ 40
Bursting strength — Wet	EN ISO 13938-1	kPa	≥ 40	Not required	≥ 40	Not required
Tensile strength — Dry	EN 29073-3	N	≥ 20	≥ 20	≥ 20	≥ 20
Tensile strength — Wet	EN 29073-3	N	≥ 20	Not required	≥ 20	Not required

a Test conditions: challenge concentration 10^8 CFU/g talcum and 30 min vibration time.

b The Least Significant Difference (LSD) for I_B when estimated using EN ISO 22610, was found to be 0,98 at the 95 % confidence level. This is the minimum difference needed to distinguish between two materials thought to be different. Thus materials varying by up to 0,98 I_B are probably not different; materials varying by more than 0,98 I_B probably are different. (The 95 % confidence levels means that an observer would be correct 19 times out of 20 to accept these alternatives.)

c I_B = 6,0 for the purpose of this document means: no penetration. I_B = 6,0 is the maximum achievable value.