## INDEX

# INSTRUCTIONS FOR MEDICAL DEVICES: HIGH PERFORMANCE GOWNS AND DRAPES (C_HP, TTR_TELO_HP) AND STANDARD PERFORMANCE GOWNS AND DRAPES (C_SP, TTR_TELO_SP)

**Introduction:**
A medical product according to Standard EN 13795. Surgical gowns and drapes are medical products. As such, they have to fulfil the basic demands stipulated in the standard series (EN 13795, 2003, 2005, 2006). Their relevant properties, such as a barrier effect, purity, low particle release rates and strength are stipulated in EN 13795–1 (2003), the test methods in EN 13795–2 (2005) and the tolerances to be fulfilled for qualifying as a medical product in EN 13795–3 (2006). For various types of operations, different product qualities (performance classes) are defined as:

- *High performance,* for operations with a high risk of infection and penetration by liquids (C_HP, TTR_TELO_HP);
- *Standard perfomance,* for operations where these risks are lower (C_SP, TTR_TELO_SP).

**Intended use**
These medical devices are meant to be used by surgeons and the medical team attending surgeries in the operating room.

**Content**
The devices are supplied in non-sterile conditions in polybags in carton boxes. Beneath the label of each device there is a chip that tracks the number of reconditioning cycles (washing and sterilization) to which the device is subject. A printed grid can be also added.

**Information on connecting with other devices**
The device is used singularly without any external connection. There are no accessories to be added.
Any other use than this is forbidden.

**Liability limits**
The manufacturing of the product is with the purpose of ensuring a high level of safety, within the parameters defined by this Annex.
The manufacturer assumes no responsibility in the case of using the product in the below listed conditions described as as improper use.

**Improper use**
It is intended for improper use of the product to be used in the following conditions:
• What is not specifically covered by the instructions
• Failure to comply with the manufacturer's instructions
• Total or partial failure to comply with the instructions
• Unsuitable storage
• Use for purposes other than the one set for the device
• Use beyond the predetermined life cycle (70 washes)
• Use with cut and/or injured fibers of the device
• The wrong cleaning/sterilization operation

**Performance and side effects**
Extremely shock-resistant.
The device is manufactured with allergy-free materials , also in consideration of particularly sensitive patients, there are no side effects with the correct use of the device.

**Storage and transportation**
The device does not require special care and attention during storage.
Store in a safe place, where the device cannot be cut, abrasions or come into contact with particular substances that can contaminate it and cause deterioration.

Storage must be carried out by ensuring a temperature between 0 ° C and 35 ° C.

**Handling**
The movement of the device takes place by manual lifting of the same. Due to its simplicity and lightness the device does not require specific handling tools.

**Assembly**
The device does not require assembly as it is supplied folded. The device is supplied in non-sterile conditions and can be used as it is or further to sterilization.

**Adjustment**
The device does not need adjustment. The only possible adjustments (in the case of the overalls) consist in closing the press-studs on the collar and the laces on the back panel. The adjustment of the press buttons and/or laces is up to the user.

**Use**
After the delivery of the finished device, the user must follow at least the below listed indications:
a) Do not clean with abrasive products. Avoid contact with solvents and chemical products, in particular strong oxidizing agents.
b) Wash and sterilize exclusively as indicated in the following parts related to the reconditioning.
c) Flammable device
d) In case of allergy to the material, quit using it immediately and consult the doctor.
e) In case of mutations of the device, such as discoloration, cuts, abrasions, degradation or other, immediately suspend its use and eliminate the device in compliance with current regulations.

Before use, always make sure that the device is not damaged and that it is correctly cleaned and sterilized. In the case of gowns:
• Open the press buttons (if any) on the collar of the gown;
• Insert the surgical gown over the garments, paying attention to accidental knocks or contacts with external items present in the surrounding environment that could cut, ruin or contaminate the materials composing the gowns;
• Make sure you wear the gown correctly;
• Close the collar of the gown with the appropriate press buttons;
• Close the gown behind the back by tieing the appropriate laces.

# RECONDITIONG IN CASE OF INDUSTRIAL WASHING

## CHRISTEYNS's washing reccomendations:

| Phase of the cycle | Time (min) | Temperature | Water level | Ratio | Liters | Product | Ph | Detergent | rpm |
|---|---|---|---|---|---|---|---|---|---|
| Soak | 4 | Cold | Medium | 1/5 | 80 | Non iogenic tensio active agent with alkali booster | 10,5<ph<11 | Mulan Intensiv 3 sec<br>Smart Alkaline 5 sec | 40 |
| Pre wash | 8 | 70°C | Medium | 1/5 | 0 | | | | 35 |
| Drain | | | | | | | | | |
| Mainwash 1 | 4 | 70°C | Medium | 1/5 | 80 | Non iogenic tensio active agent with alkali booster | 10<ph<10,5 | Mulan Intensiv 2 sec<br>Smart Alkaline 2 sec | 35 |
| Mainwash 2 | 10 | 70°C | | | | Bleaching and hygiene agent with alkali booster | 9,5 | Personril 7 sec | 45 |
| Cooldown | | 45°C | | | | | | | 750 |
| Drain | | | | | | | | | |
| Rinse 1 | 4 | 40°C | High | 1/7 | 110 | Tension active removal agent | | Osmafin rinse 5 sec | 700 |
| Drain | | | | | | | | | |
| Rinse 2 | 3 | 35°C | High | 1/7 | 110 | | | | 700 |
| Drain | | | | | | | | | |
| Rinse 3 | 3 | 30°C | High | 1/7 | 110 | | | | 700 |
| Drain | | | | | | | | | |
| Rinse 4 | 5 | Cold | Medium | 1/7 | 110 | Neutralization agent (formic acid) | 5,5<ph<6,0 | Neutrapur forte 8 sec | 825 |
| Drain | | | | | | | | | |

**Note**:
WASHING MACHINES SHOULD BE LOADED AT 70% OF THE LOADING VALUE.
CYCLE TIME: 90 min

## DRY

| | |
|---|---|
| Inlet temperature (900s) | 145°C |
| Inlet temperature | 130°C |
| Outlet temperature | 90°C |
| End temperature | 90°C |

## Autoclave

Norm UNI EN ISO 17665-1
Sterilising media is saturated steam with active removal of the air.

| Steam temperature (Celsius scale) | minutes/time |
|---|---|
| 134° | 3 |

# RECONDITIONG IN CASE OF NON INDUSTRIAL WASHING


| | | | | |
|---|---|---|---|---|
| Maximum washing temperature 60 °<br>Delicate wash | Do not bleach | Do not iron | Do not dry clean | Drying at low temperature |

## WASH PRIOR TO ANY USE

**Notes and warnings:**

1. Loading: 70% of nominal load (i.e.: Capacity: MAX 7kg - actual load: 4.9 kg) / Cycle time: max 90 min with prewash;
2. Recommended 2 preventive rinses in cold water to remove blood stains;
3. Recommended fresh water;
4. Wash separately from cotton;
5. No oxidizing whitening agents should be used, these agents include sodium hypochlorite, hydrogen peroxide and peracetic acid (PAA). Do not use oxidizing bleaches. The use of bleach can cause a loss of color and damage to the water repellent finish.
6. Recommended use of neutral pH /mild chemical detergent;
7. Centrifuge max 825 rpm;8. Do not use fabric softener;
9. Do not exceed with the use of detergent

## Autoclave

***Automatic Autoclave set process**

Norm UNI EN ISO 17665-1
Sterilizing media is saturated steam with active removal of the air.

| Steam temperature (Celsius scale) | minutes/time |
|---|---|
| 134° | 3 (hold time) |

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