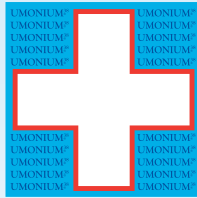


DETERGENT- DISINFECTANT
MEDICAL DEVICE
CLASS IIa



UMONIUM³⁸

NEUTRALIS TISSUES



✓ FORMULA FREE FROM

- CMR** COMPONENT
- ENDOCRINE DISRUPTOR

“ Disinfecting
environments at risk ”

SPORICIDE



UMONIUM³⁸ **NEUTRALIS TISSUES** is the first, completely safe cleaning and disinfectant wipe, even in embryonic environments. It kills germs within 5 seconds. Developed for high-risk environments (resuscitation, neonatal departments, maternity wards, IVF laboratory, etc.) It can be used to clean and disinfect fragile materials such as fibre optic, polycarbonate, latex, plexiglass, etc. The wipes do not dry out in the box.

** Carcinogenic, Mutagenic or Reprotoxic

 **laboratoire
HUCKERT'S**
INTERNATIONAL
mastered disinfection





UMONIUM³⁸ NEUTRALIS TISSUES

One 20 x 20cm wipe treats
an area of 3 m².



✓ FORMULA FREE FROM

- CMR** COMPONENT
- ENDOCRINE DISRUPTOR



INDICATIONS

Cleaning and disinfection of non-invasive medical devices.

COMPOSITION

White non-woven wipes (20cm x 20cm) made of 50% wood pulp and 50% polyester and soaked in a solution of UMONIUM³⁸ **NEUTRALIS**: N-benzyl-N-dodecyl-N, N-dimethyl-ammonium chloride/N-benzyl-N, N-dimethyl-N-tetradecyl-ammonium chloride. 11.9g/L.

The impregnation solution is classified as a class IIb medical device.

REGULATORY STANDARDS

- The bactericidal, fungicidal and sporidicidal activity of the soaked wipe has been validated according to standards ASTM 2967-15 and EN 16615
- The bactericidal, fungicidal, levoricidal, mycobactericidal and virucidal activity of the impregnation solution has been validated according to EN 13727, EN 14561, EN 13624, EN 14562, EN 14348, EN 14563 and EN 14476
- Compliant with ED 93/42/EEC relating to medical devices. (Appendix II, excl.§4)
- Quality and traceability guaranteed by ISO 9001:2015 and EN ISO 13485:2016
- MEA (Mouse Embryo Assay) validation
- HSSA (Human Sperm Survival Assay) validation
- CE marking 1639

INSTRUCTIONS FOR USE

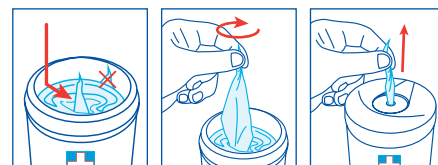
Cleaning/Pre-disinfection: Take out a wet wipe. Wet wipe to eliminate all dirt. **Disinfection:** Take out a new wet wipe. Wipe the clean devices for at least 5 seconds. Leave to dry or rinse with water* (or with a cloth dampened with water*) if necessary. Make sure to fully close the cover after use.



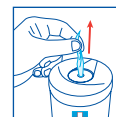
PROPERTIES

- Class IIa medical device
- Detergent- disinfectant wipe with a broad spectrum of activity
- Non-toxic, no dangerous vapours
- LD₅₀ (rat): > 5840 mg/kg
- Non-corrosive: pH-neutral
- Ready-to-use product, non-irritating for the skin (no transdermal toxicity)
- Free from aldehyde, peroxide and biguanide, and other carcinogenic, mutagenic, or reprotoxic components
- Non-coagulant
- Non-flammable
- Bactericide, fungicide and sporicide activities
- 100% compatible on fibre optic, rubber, polycarbonate, acrylic compound, glass, Pyrex, PU, PVC, HDPE, PET, neoprene, latex, silicone, paints and stainless steel 410
- Effective, fast-acting and efficient (dissolves blood)
- Effective in the presence of organic materials
- Active within 5 seconds
- Residual on non-rinsed surfaces (bacteriostatic film)
- No residue after rinsing
- Stability: 36 months date of manufacture
- Colourless, fragrance-free product
- Safety validated up to the embryonic environment

PROCEDURE FOR USE



STEP 1: CLEANING/PRE-DISINFECTION

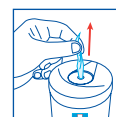


Take out a wet wipe



Wet wipe to eliminate all dirt

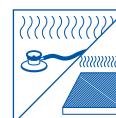
STEP 2: DISINFECTION



Take out a new wet wipe



Wipe the clean devices for at least 5 seconds



Leave to dry **OR** rinse with water* (or with a cloth dampened with water*) if necessary

| ITEM No. | NAME | BOX |
|----------|----------------------------------|---------|
| PF 10769 | Box of 100 wipes (20 x 20cm) | 6 x 100 |
| PF 10779 | 500 individual packs (20 x 20cm) | 500 x 1 |

* Clean drinking water at room temperature

** Carcinogenic, Mutagenic or Reprotoxic