DETERGENT- DISINFECTANT
MEDICAL DEVICE
CLASS IIb

EVALUATION 99,4% BIODEGRADABILITY

PACKAGING VEGETAL PLASTIC

# UMONIUM 38®

## NEUTRALIS SPRAY

ECO FRIENDLY

✓ FORMULA FREE FROM
- ➜ CMR** COMPONENT
- ➜ ENDOCRINE DISRUPTOR

“Protecting what is most valuable”

FLASH DISINFECTION
AFTER 30 SEC.

VALIDATION MOUSE EMBRYO ASSAY

VALIDATION HUMAN SPERM SURVIVAL ASSAY






**UMONIUM 38® NEUTRALIS SPRAY** is a Detergent- leading disinfectant for high-risk areas and sensitive environments (neonatology (neonatal rehabilitation), IVF/AMP, general gynaecology, maternity and obstetrics, etc.). Ready to use and classified as a medical device, it validates the highest standards of effectiveness on all pathogens while meeting the reproductive and embryo-toxicity tests. Completely odourless and safe, it can be used together for the cleaning and disinfection of all surfaces, equipment and the most sensitive invasive and non-invasive medical devices. The dual-function nozzle sprays either a foam or a fine spray for optimal disinfection.

laboratoire HUCKERT'S INTERNATIONAL
*mastered disinfection*

MADE IN BELGIUM

** Carcinogenic, Mutagenic or Reprotoxic

www.huckerts.net

# UMONIUM 38®
# NEUTRALIS SPRAY

500ml amounts to 500 sprays and treats an area of 100m².




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## INDICATIONS

Colourless, odourless. Cleaning and disinfection of invasive medical devices before sterilisation. Cleaning and disinfection for non-invasive medical devices and their surfaces. Transport of soiled instruments.

## COMPOSITION

N-benzyl-N-dodecyl-N, N-dimethyl-ammonium chloride/N-benzyl-N, N-dimethyl-N-tetradecyl-ammonium chloride. 3.3g/L.

## REGULATORY STANDARDS

- 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

**Transport**: Set the spray to the "foam" position and cover the devices with the foam. Make sure to cover well to limit evaporation. **Cleaning/Pre-disinfection**: Set the spray to the "foam" position. Spray and scrub the devices to eliminate all dirt. Rinse thoroughly with water* or using a cloth dampened with water* if you're cleaning surfaces. **Disinfection**: Set the spray to the "fine" position. Spray over clean devices. Ensure a minimum contact time of 5 minutes. If you're cleaning invasive medical devices: Rinse with water*. If you're cleaning non-invasive medical device surfaces: Leave to dry or rinse with water* (or with a cloth dampened with water*) if necessary.

## PROPERTIES

- Class IIb medical device
- Detergent- disinfectant with a broad spectrum of activity
- Non-toxic, no dangerous vapours
- $LD_{50}$ (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 (including MRSA and other antibiotic resistant strains), fungicide, mycobactericide and virucide (including human coronavirus)
- 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
- Acts within 30 seconds
- Residual on non-rinsed surfaces (bacteriostatic film)
- No residue after rinsing
- Stability: 36 months date of manufacture
- Colourless, fragrance-free product
- Complete safety in the environment of an embryo
- No volatile organic compounds released (VOC).



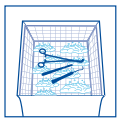

| ITEM No. | NAME | BOX |
|---|---|---|
| PF 12608 | 500mL spray bottle | 30 x 500mL |
| EMB 0099 | 100 towels UMONIUM38 Wipes | 12 items |

# PROCEDURE FOR USE

## STEP ❶ : TRANSPORT



Set the spray to the "foam" position



Covering the devices with foam



Make sure to cover well to limit evaporation

## STEP ❷ : CLEANING/PRE-DISINFECTION



Set the spray to the "foam" position and spray



Scrub the devices to eliminate all dirt

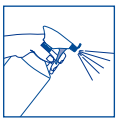


Rinse thoroughly with water* or using a cloth dampened with water* if you're cleaning surfaces

## STEP ❸ : DISINFECTION



Set the spray to the "fine" position



Spray



Minimum contact time 5 minutes



OR



**If invasive medical devices**: Rinse with water*
OR **If non-invasive medical device surfaces**: Allow to dry or rinse with water* (or with a damp cloth*) if necessary

# TECHNICAL DETAILS

| Standards | Target organisms | | Contact time (min.) | |
|---|---|---|---|---|
| | | | Condition clean | Dirty condition |
| EN 13727 | BACTERIA | *S. aureus, E. hirae, P. aeruginosa* | 30 sec. | 1 |
| | | *E. faecalis (vancomycin-resistant), E. coli (carbapenem-resistant), K. pneumoniae (carbapenem-resistant), S. aureus (methicillin-resistant)* | 30 sec. | - |
| EN 13697 | BACTERIA | *S. aureus, E. hirae, E. coli, P. aeruginosa* | 10 | 15 |
| | | *S. typhimurium, E. cloacae, L. brevis* | - | 15 |
| EN 16615 | BACTERIA | *S. aureus, E. hirae, P. aeruginosa* | 1 | 1 |
| EN 14561 | BACTERIA | *S. aureus, E. hirae, P. aeruginosa* | - | 30 |
| EN 13624 | FUNGI | *C. albicans* | 5 | 10 |
| | | *Candida auris* | 5 | - |
| EN 13697 | FUNGI | *C. albicans* | 10 | 15 |
| EN 16615 | FUNGI | *C. albicans* | 1 | - |
| | | *C. Auris* | 30 sec. | 30 sec. |
| EN 14562 | FUNGI | *C. albicans, A. niger* | 10 | 10 |
| EN 14476 | VIRUSES | Norovirus, Adenovirus, Poliovirus | 10 | 10 |
| | | Human coronavirus, *Vaccinia virus* | 5 | - |
| EN 16777 | VIRUSES | *Vaccinia virus* | - | 30 |
| EN 17111 | VIRUSES | *Vaccinia virus* | 60 | - |
| EN 14348 | MYCOBACT. | *M. avium, M. terrae* | 10 | 10 |
| EN 14563 | MYCOBACT. | *M. avium, M. terrae* | 10 | 10 |

* Clean drinking water at room temperature
** Carcinogenic, Mutagenic or Reprotoxic

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