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
Odourless and colourless ready-to-use solution for the cleaning and disinfection of invasive medical devices prior to sterilization, non-invasive medical devices, and surfaces of non-invasive medical devices.

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).

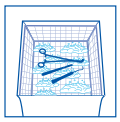


ITEM No.	NAME	BOX
PF 12608	500mL spray bottle	30 x 500mL
EMB 0099	100 towels UMONIUM^{38} Wipes	12 items

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

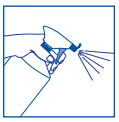

Set the spray to the "foam" position and spray


Scrub the devices to eliminate all dirt

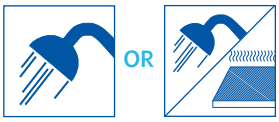

Rinse thoroughly with water* or using a cloth dampened with water* if you're cleaning surfaces

STEP ❸ : DISINFECTION


Set the spray to the "fine" position


Spray


Minimum contact time 5 minutes



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	Contact time (min.) 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		*S. aureus, E. hirae, E. coli, P. aeruginosa*	10	15
		S. typhimurium, E. cloacae, L. brevis	-	15
EN 16615		*S. aureus, E. hirae, P. aeruginosa*	1	1
EN 14561		*S. aureus, E. hirae, P. aeruginosa*	-	30
EN 13624	FUNGI	*C. albicans*	5	10
		Candida auris	5	-
EN 13697		*C. albicans*	10	15
EN 16615		*C. albicans*	1	-
		C. Auris	30 sec.	30 sec.
EN 14562		*C. albicans, A. niger*	10	10
EN 14476	VIRUSES	Norovirus, Adenovirus, Poliovirus	10	10
		Human coronavirus, *Vaccinia virus*	5	-
EN 16777		*Vaccinia virus*	-	30
EN 14348	MYCOBACT.	*M. avium, M. terrae*	10	10
EN 14563		*M. avium, M. terrae*	10	10

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

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