DETERGENT - DISINFECTANT
MEDICAL DEVICE
CLASS IIa

UMONIUM 38®

NEUTRALIS TISSUES

MADE IN BELGIUM

ECO FRIENDLY

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

VALIDATION MOUSE EMBRYO ASSAY

VALIDATION HUMAN SPERM SURVIVAL ASSAY

* Carcinogenic, Mutagenic or Reprotoxic

laboratoire HUCKERT'S INTERNATIONAL
mastered disinfection

www.huckerts.net

NOTES:

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laboratoire HUCKERT'S INTERNATIONAL *mastered disinfection*

GENERAL AND REGULATORY INFORMATION SHEET

UMONIUM38® **NEUTRALIS TISSUES** are designed, produced and controlled by Laboratoire Huckert's International under the guidelines for the **ISO 9001** and **ISO 13485** quality management systems.

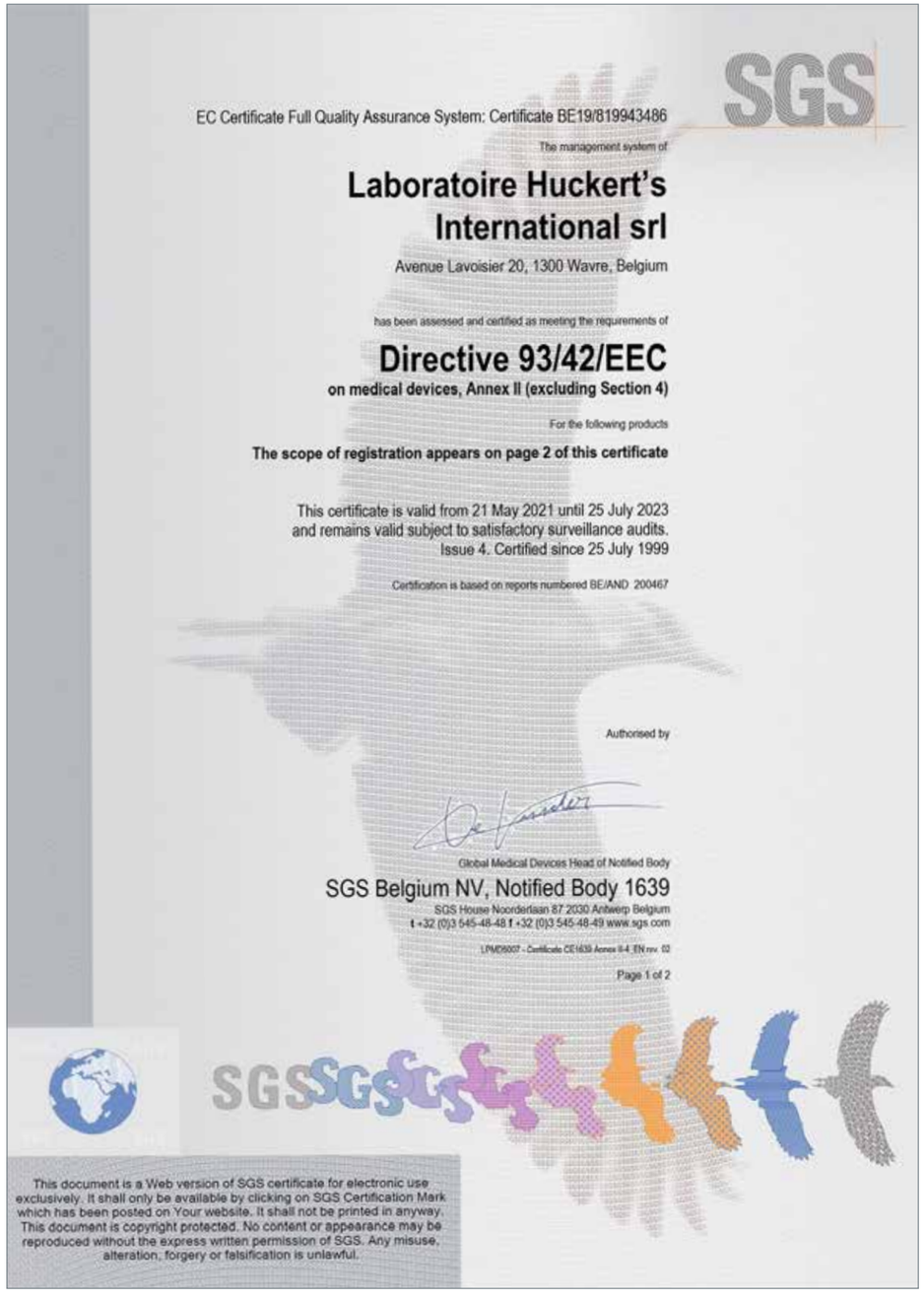
UMONIUM38® **NEUTRALIS TISSUES** are broad-spectrum cleaning and disinfectant wipes. They can be used to disinfect non-invasive medical devices

Consequently, they are a **class IIa medical device** in their own right. As such, they carry the **CE mark**, in compliance with **Directive 93/42/EEC**.

To offer our clients a premium product, **controls are performed at 76 points** from acceptance of the raw materials to the release of products on the market and beyond the product's life cycle.

Besides, our products are quarantined for 120 hours to guarantee that **full compliance and assurance are applied to the products released**.

laboratoire HUCKERT'S INTERNATIONAL la désinfection maîtrisée
MADE IN BELGIUM
UMONIUM38® NEUTRALIS TISSUES



SGS

EC Certificate Full Quality Assurance System: Certificate BE19/819943486

The management system of

Laboratoire Huckert's International srl

Avenue Lavoisier 20, 1300 Wavre, Belgium

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

The scope of registration appears on page 2 of this certificate

This certificate is valid from 21 May 2021 until 25 July 2023
and remains valid subject to satisfactory surveillance audits.
Issue 4. Certified since 25 July 1999

Certification is based on reports numbered BE/AND 200467

Authorised by

Global Medical Devices Head of Notified Body

SGS Belgium NV, Notified Body 1639

SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

LPMD6007 - Certificate CE1639 Annex II-4 EN rev. 02

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Laboratoire Huckert's International srl

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

Issue 4

Detailed scope

Concentrated UMONIUM38® dedicated to disinfection of invasive medical devices (Surgical instruments) and surface disinfection of non-invasive medical devices.

Ready to be used UMONIUM38® dedicated to disinfection of invasive medical devices (Surgical instruments) and surface disinfection of non-invasive medical devices.

Details
Surface disinfectants for non invasive medical devices
- Umonium 38 ® Equipments (125ml, 1L, 5L, 25L)
- Umonium 38 ® Medical Tissues (1, 10, 100, 95)
- Umonium 38 ® Neutralis tissue (1, 100, 95 wipes)

Disinfectants for invasive and non-invasive medical devices, with the exclusion of contact lenses

- U38 Instrument (125ml, 1L and 5L)
- U38 Instrument & Equipment (125ml, 1L and 5L)
- U38 Medical Spray (spray 250ml, 500ml and 1L)
- U38 Labocid (25L) - U38 Neutralis (125ml, 1L and 5L)
- U38 Neutralis Spray (250 and 500 ml)
- U38 Sterily (125ml, 1L and 5L

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.

laboratoire HUCKERT'S INTERNATIONAL la désinfection maîtrisée

MADE IN BELGIUM

UMONIUM38® NEUTRALIS TISSUES

The management system of

Laboratoire Huckert's International sprl

Avenue Lavoisier 20
1300 Wavre, Belgium

Has been assessed and certified as meeting the requirements of

ISO 9001:2015

For the following activities

Design, development, manufacture and distribution of hygiene products and disinfectants for invasive and non-invasive medical devices, with the exclusion of contact lenses.

This certificate is valid from 26/01/2021 until 25/07/2023 and remains valid subject to satisfactory surveillance audits.
Issue 13. Certified since 25/07/1999.
Re certification audit due before 25/06/2023.

Authorised by

Pieter Weterings
Certification Manager
SGS Belgium NV
SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

Accreditation Number
005-QMS
EN ISO/IEC 17021-1:2015

SGS-BE-01-15 01 0109

Certificate BE19/819943487

The management system of

Laboratoire Huckert's International srl

Avenue Lavoisier 20
1300 Wavre, Belgium

has been assessed and certified as meeting the requirements of

ISO 13485:2016
EN ISO 13485:2016

For the following activities

Design, development, manufacture and distribution of disinfectants for invasive and non invasive medical devices, with the exclusion of contact lenses.

This certificate is valid from 21 May 2021 until 25 July 2023
and remains valid subject to satisfactory surveillance audits.
Issue 3. Certified since 25 July 1999
Re certification audit due before 25 June 2023

Authorised by

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SGS Belgium 13485-2 0308

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Accreditation Number
005-GMS
EN ISO/IEC 17021-1:2015

laboratoire HUCKERT'S INTERNATIONAL la désinfection maîtrisée
MADE IN BELGIUM
UMONIUM 38® NEUTRALIS TISSUES

laboratoire HUCKERT'S INTERNATIONAL mastered disinfection.	Document de Référence	R-DIR-01-Politique Qualité Edition : 1.3 Page **1** sur **1**
	Politique Qualité	

Cette politique sert de cadre à l'élaboration des objectifs qualité et des plans d'amélioration.
Elle est établie par la Direction, et est communiquée et expliquée à l'ensemble des collaborateurs.

- **Le Laboratoire Huckert's International** fondé en 1957, a développé des **compétences** remarquables dans le domaine de **l'hygiène**. C'est pourquoi nous voulons être reconnus comme **les spécialistes** de ce domaine en proposant des produits originaux très **haut de gamme,** présentant à la fois des caractères uniques de **performance et de sécurité** tant pour les hommes que pour le matériel et l'environnement.

- Face à la concurrence des grands groupes multinationaux, notre politique consiste à exploiter des **marchés de niche rentables** qui soient à la recherche de produits d'exception tels que nous les fabriquons

- Aussi nous devons faire preuve d'une grande **réactivité** en étant **à l'écoute** attentive de nos clients et en recherchant toujours **leur satisfaction** totale par un service exceptionnel et une garantie donnée sur tous nos produits.

- Nous voulons sans cesse parfaire notre **communication commerciale** à travers une information documentaire scientifique d'excellence et la qualité de nos interventions.

- Nous sommes également soucieux de la crédibilité de notre Entreprise, l'entreprise s'engage à satisfaire aux exigences applicables par notre système de qualité **ISO 9001 – ISO 13485** et notre certification européenne **MDD 93/42/CEE** qui assurent la **parfaite traçabilité** et la reproductibilité de nos lots, l'équipe met tout en œuvre pour assurer la conformité du système vers la nouvelle réglementation **MDR (EU) 2017/745** ainsi que la transition vers le nouveau règlement **BPR (EU) 528/2012.**

- De même nous attendons de nos **fournisseurs** un service de qualité qui permette d'aller vers un **partenariat** basé sur la confiance et l'échange.

- Désireux d'aller sans cesse de l'avant, nous voulons nous **développer** dans notre métier, grâce à une **R&D** souple, rapide et maîtrisée et en optimisant nos **ressources** humaines et financières.

- Enfin **en impliquant** l'ensemble de nos **collaborateurs** dans des objectifs définis annuellement, nous voulons promouvoir un processus **d'amélioration continue** et d'expansion constante.

« Ne remplacez pas un danger biologique par un risque chimique »

12th October 2021
Florence Huckert,
CEO

12th October 2021
Valérie Huckert,
CEO

SUSTAINABLE DEVELOPMENT POLICY

Laboratoire Huckert's International bases its success on values other than simple economic performance. Since its creation in **1957**, the family-run company has applied a Corporate Social Responsibility (CSR) approach that is deeply integrated into its strategy. **In real terms, this translates into formal engagements on an environmental, societal and economic level.**

Sustainable development forms an integral part of the Laboratoire Huckert's International quality management system. We seek first and foremost to have our employees adhere to our Family Company values. **Quality, Health and Ethics are at the heart of all our approaches.** Ranging from the non-harmful nature of our products for OPME (Operator, Patient, Material and Environment) to the reduction of the environmental impact dictated by our activity.

See our on-line documentation for further information: **http://www.huckerts.net/emailing/politique_de_developpement_durable_en.pdf**

IMPREGNATED WIPE COMPOSITION

UMONIUM38® **NEUTRALIS TISSUES** comprise non-woven wipes soaked in a UMONIUM38® solution.

IMPREGNATION SOLUTION COMPOSITION

Principal anti-microbial active ingredient N-benzyl-N-dodecyl-N, N-dimethyl-ammonium chloride/Nbenzyl-N, N-dimethyl-N-tetradecyl-ammonium chloride. 11.9 g/L

Other ingredients:
- Surfactants
- Sequestering agents
- Excipients

Physico-chemical specifications :
- pH neutral (non-corrosive)
- Clear transparent solution

WIPE COMPOSITION

- 50% wood pulp/50% polyester
- Interwoven by hydraulic process
- Colour: white

UMONIUM38® **NEUTRALIS TISSUES** are **cleaning and disinfectant wipes with total innocuity even in an embryonic environment** (see section on biocompatibility). They contain no carcinogenic, mutagenic or reprotoxic (CMR) components, no phthalates and no endocrine disruptors. This **unperfumed** and **un coloured product has been developed especially for use in sensitive environments** such as neonatal incubators, IVF (In Vitro Fertilization) laboratories, MAP (Medically Assisted Procreation) laboratories, research laboratories and Class P3 and P4 confined spaces, etc. (see section on biocompatibility).

Its active components work in synergy with the other formula ingredients so as to provide a **broad-spectrum** microbicidal activity. In addition to the **antimicrobial action**, the presence of surfactants allows for procuring a **surface cleaning and degreasing** action. This product can, therefore, be used during the pre-disinfection stage and the disinfection stage.

Its **neutral pH** ensures **excellent chemical compatibility** with multiple materials (see section on material compatibility).

PACKAGING COMPOSITION

BOXES OF 100 WIPES, 20 X 20 CM

UMONIUM[38®] **NEUTRALIS TISSUES** come in an HDPE (High-Density PolyEthylene) box dispenser. Each box contains a PET/PE (polyethylene terephthalate/ polyethylene) sachet containing 100 wipes measuring 20 x 20 cm. The cover is made of PP (polypropylene).

SINGLE-DOSE SACHETS

UMONIUM[38®] **NEUTRALIS TISSUES** also come in the form of individual sachets (20 x 20 cm). The sachets are made up of Kraft/PE/Aluminium/ Surlyn paper.

STABILITY AND CONSERVATION CONDITIONS

UMONIUM[38®] **NEUTRALIS TISSUES** are a ready-to-use product supplied in a box dispenser or single-dose sachet.

STORAGE

The active substance in UMONIUM[38®] **NEUTRALIS TISSUES** is stable up to 90°C. Studies on the storage of UMONIUM[38®] **NEUTRALIS TISSUES** for 6 months at 60°C demonstrated the product's stability under these conditions.

However, it is recommended the product be kept under best conservation practices for chemicals, i.e. in its **original container, in a cool, well-ventilated area, away from any heat sources and out of direct sunlight**.

STABILITY

➤ **Unopened box and sachet:** 36 months from the date of manufacture shown on the label.

➤ **Box after first use:** provided the wipes remain in the **closed** dispenser box, the stability period of 36 months from the date of manufacture is upheld.

MICROBICIDAL EFFICACY

In Europe, the microbicidal efficacy of a disinfectant must be assessed per the European standards specified in **Standard EN 14885 (Applications of European standards to chemical antiseptics and disinfectants)**. This document specifies, activity sector by activity sector, the standards with which disinfectants must comply in order to support the microbicidal activity claims.

The microbicidal activity of UMONIUM 38® **NEUTRALIS TISSUES** has been validated according to standard EN 14885. **The battery of tests required to verify the product's efficacy was performed by independent laboratories.**

In most cases, the activity of UMONIUM 38® **NEUTRALIS TISSUES** was validated under both clean and dirty conditions. The results show that the product retains all its efficacy even when dirt is present. Furthermore, the tests performed showed that the effective concentration is lower than the concentration of use for UMONIUM 38® **NEUTRALIS TISSUES**, which adds **an additional safety margin to the product's efficacy.**

BACTERICIDE

Standard	Strain	Conditions	Time	Active concentration (% compared to the ready-to-use product)	
EN 1276	*E. hirae* *P. aeruginosa* *S. aureus* *E. coli*	Clean	5 mins	*E. hirae* *P. aeruginosa* *S. aureus* *E. coli*	21% 21% 21% 21%
		Dirty (BSA)	10 mins	*E. hirae* *P. aeruginosa* *S. aureus* *E. coli*	1% 21% 5% 1%
EN 13727	*E. hirae* *P. aeruginosa* *S. aureus* **Additional strains :** *E. faecalis (vancomycin-resistant)* *E. coli (carbapenem-resistant)* *K. pneumoniae (carbapenem-resistant)* *S. aureus (methicillin-resistant)*	Clean	30 seconds	*E. hirae* *P. aeruginosa* *S. aureus* *E. faecalis (vancomycin-resistant)* *E. coli (carbapenem-resistant)* *K. pneumoniae (carbapenem-resistant)* *S. aureus (methicillin-resistant)*	27% 27% 27% 27% 27% 27% 27%
EN 13697	*E. hirae* *P. aeruginosa* *S. aureus* *E. coli* **Additional strains :** *S. typhimurium* *E. cloacae* *L. brevis*	Clean	10 mins	*E. hirae* *P. aeruginosa* *S. aureus* *E. coli*	27% 27% 27% 27%
		Dirty (BSA)	15 mins	*E. hirae* *P. aeruginosa* *S. aureus* *E. coli*	5% 5% 5% 1%
		Dirty (skimmed milk)		*S. thyphimurium* *E. cloacae* *L. brevis*	5% 5% 5%
EN 14561	*E. hirae* *P. aeruginosa* *S. aureus*	Dirty (BSA + SRBC)	30 mins	*E. hirae* *P. aeruginosa* *S. aureus*	3% 3% 3%
EN 16615	*E. hirae* *P. aeruginosa* *S. aureus*	Clean	1 min	*E. hirae* *P. aeruginosa* *S. aureus*	100% 100% 100%
ASTM 2967-15	*S. aureus* *A. baumannii*	Clean	5 seconds	*S. aureus* *A. baumannii*	100% 100%

IMPREGNATION LIQUID

IMPREGNATED WIPE

The bactericidal efficacy was verified in accordance with European standard **EN 14885 "Chemical antiseptics and disinfectants – Application of European standards to chemical antiseptics and disinfectants"**. In accordance with this standard, the battery of tests to be performed combined tests on the impregnation liquid with tests carried out directly using the wipe (EN 16615). Additional tests were performed directly using the wipe according to American standard ASTM 2967-15.

The results of the tests shown in the above table (impregnation liquid) show, that when tested, the effective concentration is lower than the concentration of impregnation liquid in the wipe (100%), which adds an additional safety margin to the product efficacy

Disinfection is always carried out on clean surfaces that have thus undergone a preliminary cleaning stage. It may be that the cleaning was poorly performed, or that dirt residues invisible to the naked eye remain, especially in hard to reach areas. It is therefore important that a disinfectant is also effective under imperfect conditions.

The tests performed on UMONIUM 38® **NEUTRALIS TISSUES** under dirty conditions showed that **the product retains all its efficacy, even in the presence of dirt.**

N/A: Not applicable - BSA: Bovine Serum Albumin - SRBC: Sheep Red Blood Cells

YEASTICIDE/FUNGICIDE

Standard	Strain	Conditions	Time	Active concentration (% compared to the ready-to-use product)		
EN 1650	*C. albicans*	Clean	10 mins	*C. albicans*	5%	IMPREGNATION LIQUID
		Dirty (BSA)		*C. albicans*	5%	
EN 13624	*C. albicans*	Clean	5 mins	*C. albicans*	27%	
		Dirty (BSA + SRBC)	10 mins	*C. albicans*	21%	
EN 13697	*C. albicans* *A. niger*	Clean	10 mins	*C. albicans*	27%	
		Dirty (BSA)	15 mins	*C. albicans* *A. niger*	21% 21%	
EN 14562	*C. albicans* *A. niger*	Clean	10 mins	*C. albicans* *A. niger*	21% 21%	
		Dirty (BSA + SRBC)		*C. albicans* *A. niger*	21% 21%	
EN 16615	*C. albicans*	Clean	30 seconds	*C. albicans*	100%	IMPREGNATED WIPE
ASTM 2967-15	*C. albicans*	Clean	5 seconds	*C. albicans*	100%	

The yeasticidal/fungicidal efficacy was verified in accordance with European standard **EN 14885 "Chemical antiseptics and disinfectants – Application of European standards to chemical antiseptics and disinfectants"**. In accordance with this standard, the battery of tests to be performed combined tests on the impregnation liquid with tests carried out directly using the wipe (EN 16615). Additional tests were performed directly using the wipe according to American standard ASTM 2967-15.

The results of the tests shown in the above table (impregnation liquid) show, that when tested, the effective concentration is lower than the concentration of impregnation liquid in the wipe (100%), which adds an additional safety margin to the product efficacy

Disinfection is always carried out on clean surfaces that have thus undergone a preliminary cleaning stage. It may be that the cleaning was poorly performed, or that dirt residues invisible to the naked eye remain, especially in hard to reach areas. It is therefore important that a disinfectant is also effective under imperfect conditions.

The tests performed on UMONIUM 38® **NEUTRALIS TISSUES** under dirty conditions showed that **the product retains all its efficacy, even in the presence of dirt**.

N/A: Not applicable - BSA: Bovine Serum Albumin - SRBC: Sheep Red Blood Cells

TUBERCULOCIDE/MYCOBACTERICIDE

Standard	Strain	Conditions	Time	Active concentration (% compared to the ready-to-use product)		
EN 14348	*M. terrae* *M. avium*	Clean	10 mins	*M. terrae* *M. avium*	22% 22%	IMPREGNATION LIQUID
		Dirty (BSA + SRBC)		*M. terrae* *M. avium*	22% 22%	
EN 14563	*M. terrae* *M. avium*	Clean	10 mins	*M. terrae* *M. avium*	22% 22%	
		Dirty (BSA + SRBC)		*M. terrae* *M. avium*	22% 22%	
No existing standard	-	-	-	-		IMPREGNATED WIPE

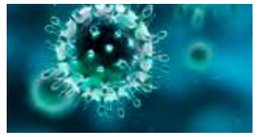
The tuberculocidal/mycobactericidal efficacy was verified in accordance with European standard **EN 14885 "Chemical antiseptics and disinfectants – Application of European standards to chemical antiseptics and disinfectants"**. The efficacy tests were carried out on the wipe's impregnation liquid. There is currently no validated standard for testing the tuberculocidal/mycobactericidal activity of impregnated wipes. Consequently, only tests carried out on the impregnation liquid could be performed.

The results of the tests shown in the above table (impregnation liquid) show, that when tested, the effective concentration is lower than the concentration of impregnation liquid in the wipe (100%), which adds an additional safety margin to the product efficacy

Disinfection is always carried out on clean surfaces that have thus undergone a preliminary cleaning stage. It may be that the cleaning was poorly performed, or that dirt residues invisible to the naked eye remain, especially in hard to reach areas. It is therefore important that a disinfectant is also effective under imperfect conditions.

The tests performed on UMONIUM 38® **NEUTRALIS TISSUES** under dirty conditions showed that **the product retains all its efficacy, even in the presence of dirt**.

BSA: Bovine Serum Albumin - SRBC: Sheep Red Blood Cells



VIRUCIDE

Standard	Strain	Conditions	Time	Active concentration (% compared to the ready-to-use product)		
EN 14476 (2013)	Poliovirus Adénovirus Norovirus murin **Additional strain :** Human coronavirus	Clean	5 mins	Human coronavirus	27%	IMPREGNATION LIQUID
			10 mins	Poliovirus Adénovirus Norovirus murin	22% 22% 22%	
		Dirty (BSA + SRBC)	10 mins	Poliovirus Adénovirus Norovirus murin	22% 22% 22%	
EN 16615	Vaccinia virus	Clean	5 mins	Vaccinia virus	100%	IMPREGNATED WIPE

The viricidal efficacy was verified in accordance with European standard **EN 14885 "Chemical antiseptics and disinfectants – Application of European standards to chemical antiseptics and disinfectants"**. The efficacy tests were carried out on the wipe's impregnation liquid. There is currently no validated standard for testing the viricidal activity of impregnated wipes. Consequently, only tests carried out on the impregnation liquid could be performed.

The results of the tests shown in the above table (impregnation liquid) show, that when tested, the effective concentration is lower than the concentration of impregnation liquid in the wipe (100%), which adds an additional safety margin to the product efficacy

Disinfection is always carried out on clean surfaces that have thus undergone a preliminary cleaning stage. It may be that the cleaning was poorly performed, or that dirt residues invisible to the naked eye remain, especially in hard to reach areas. It is therefore important that a disinfectant is also effective under imperfect conditions.

The tests performed on UMONIUM 38® **NEUTRALIS TISSUES** under dirty conditions showed that **the product retains all its efficacy, even in the presence of dirt**.

BSA: Bovine Serum Albumin - SRBC: Sheep Red Blood Cells

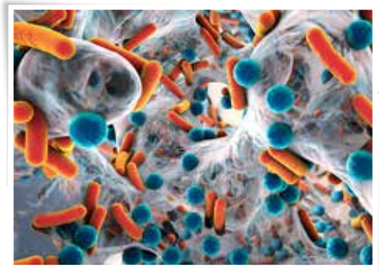
SPORICIDE

Standard	Strain	Conditions	Time	Active concentration (% compared to the ready-to-use product)		
EN 16615	*C. difficile*	Clean	1 min.	*C. difficile*	100%	IMPREGNATED WIPE
ASTM 2967-15	*C. difficile*	Clean	5 seconds	*C. difficile*	100%	

UMONIUM 38® **NEUTRALIS TISSUES** are ready-to-use cleaning disinfectant wipes.

European standard **EN 14885 "Chemical antiseptics and disinfectants – Application of European standards to chemical antiseptics and disinfectants"** does not mention any standard test to validate the sporicidal activity of a disinfectant used in the medical field. This activity was thus tested on the impregnated wipe in accordance with the protocols from standards ASTM 2967-15 and EN 16615.

BIOFILMS



Microorganisms are capable of attaching themselves to surfaces and to each other in order to form often complex and symbiotic aggregates that are called “biofilms”.

Microorganisms organized into a biofilm secrete an extracellular matrix that protects them from external aggression. Some traditional disinfectants or those based on oxidizing agents have a limited capacity to eliminate biofilms.

To date, there is no European standard to measure the efficacy of disinfectants on microorganisms organized in a biofilm, but studies performed according to protocols published the literature or adapted from these protocols give a good indication of a product’s efficacy.

Tests performed on biofilms by the Faculty of Pharmacy at the University of Ghent demonstrated the **efficacy of the impregnation liquid for UMONIUM38® NEUTRALIS TISSUES on eliminating these biofilms**. These studies were performed on biofilms of *S. aureus*, *P. aeruginosa* and *C. albicans*, which had been formed on different types of surface: steel, rubber, plastic and glass.

Reduction (log) compared to an untreated control	*S. aureus*	*P. aeruginosa*	*C. albicans*
Steel	7.22	7.22	6.22
Rubber	5.13	5.23	5.42
Plastic	6.14	8.06	6.09
Glass	7.24	8.89	3.89

Conditions: impregnation liquid for UMONIUM38® NEUTRALIS TISSUES (at 21%), 15 minutes contact time, 900 rpm.

CLINICAL TRIALS – EFFICACY AND INNOCUITY

Various clinical trials have been carried out on UMONIUM38® NEUTRALIS TISSUES or on a product in the NEUTRALIS range:

STUDY OF THE EFFICACY OF UMONIUM38® NEUTRALIS

➥ **Disinfecting incubators in a neonatal department (long-term study: data generated and analysed over a 5-month period).**

This long-term field trial relating to the efficacy of a disinfection protocol based on the use of UMONIUM38® NEUTRALIS products has allowed for collecting and analysing an impressive amount of data (1560 points*). This study was carried out within the neonatal department at the University Hospital of Siena (Italy) and demonstrated not only the efficacy of UMONIUM38® products under real conditions of use, but also the lack of secondary effects both for new-borns and for the surfaces.

https://academic.oup.com/eurpub/article/27/suppl_3/ckx187.196/4556164

NEONATAL INCUBATOR SAFETY

➥ **Clinical trial prior to the foregoing.**

A field study prior to the foregoing and over a shorter period was carried out in the Neonatal Department at the University Hospital of Antwerp. It also concluded the efficacy of the UMONIUM38® NEUTRALIS products employed under real conditions of use.

The reports on these studies and the attestations are available on simple request (**info@huckerts.net**)

*20 incubators tested; 13 points analysed per incubator over a period of 5 months

COMPATIBILITY

WITH REGARD TO MATERIALS

- Optic fibre
- Rubber
- Polycarbonate (PC)
- Acrylic compounds
- Glass
- Pyrex
- Polyurethane (PU)
- Polyvinyl chloride(PVC)
- High density polyethylene (HDPE)
- Polyethylene terephthalate (PET)
- Polypropylene (PP)
- Neoprene
- Latex
- Plexiglass
- Silicones
- Paints
- Stainless Steel 410
- Anodized aluminium
- Aluminium alloy (AL 7075)
- Titanium alloy (Ti 6AL4V)

WITH REGARD TO MEDICAL DEVICES OR SPECIFIC OBJECTS

Compatibility tests were also carried out on specific medical devices (ultrasound probes, mammography equipment, incubators, respiratory masks etc.).

Contact us by e-mail (**info@huckerts.net**) for further information.

BIOCOMPATIBILITY

The various tests performed on the UMONIUM38® range in accordance the exposure scenario for these products and additional tests performed on UMONIUM38® **NEUTRALIS TISSUES** allow for concluding that the residues from UMONIUM38® **NEUTRALIS TISSUES** are biocompatible under the recommended conditions of use and have no impact on the health of the patient or the user, which **complies with the requirements of Directive 93/42/EEC.**

HAEMOLYSIS TEST (ISO 10993-4)

Conclusion: UMONIUM38® **NEUTRALIS TISSUES** do not cause **any alteration** in blood.

SKIN SENSITIZATION TEST (EN-ISO 10993-10)

Conclusion: The residues from UMONIUM38® **NEUTRALIS TISSUES** are classed as **non-sensitizing**.

REVERSE MUTATION TEST (SHORT-TERM OECD TEST 471)

Conclusion: The residues from UMONIUM38® **NEUTRALIS TISSUES** are not **mutagenic**.

IN VITRO MAMMALIAN CELL GENE MUTATION TEST (LONG-TERM OECD TEST 476)

Conclusion: The residues from UMONIUM38® **NEUTRALIS TISSUES** do not cause **genetic mutation** in the mammalian cell cultures used.

ADDITIONAL TESTS PERFORMED SPECIFICALLY FOR CERTAIN APPLICATIONS (IVF, MAP, NEONATOLOGY, ETC.)

Like other products in the UMONIUM38® **NEUTRALIS** range, UMONIUM38® **NEUTRALIS TISSUES** are compatible with IVF (In Vitro Fertilization) and MAP (Medically Assisted Procreation) environments or with Neonatology.

MEA (MOUSE EMBRYO ASSAY) TEST

The MEA test is a functional and toxicological test, widely used to detect the toxicity and potential functional effects that could be presented by environments or surfaces that may come into contact (directly or indirectly) with gametes or embryos. This test performed in environments disinfected with UMONIUM38® **NEUTRALIS TISSUES** showed **total innocuity** of the product for embryonic cells.

HSSA (HUMAN SPERM SURVIVAL ASSAY) TEST

The HSSA test is a toxicological and functional test based on the study of the motility of sperm exposed to an agent or environment to be tested. This test performed on an environment disinfected by UMONIUM38® **NEUTRALIS TISSUES** showed a **complete absence of effect on the motility of this sperm**.

The reports on these studies are available on simple request (**info@huckerts.net**)

TOXICOLOGICAL AND ECOTOXICOLOGICAL INFORMATION

IDENTIFICATION OF THE DANGERS

- **Health:** UMONIUM38® does not present a danger to health.
- **Environment:** Not classified.

PERSONAL PROTECTION

- **Personal protective equipment:** Avoid any unnecessary exposure.
- **Hand protection:**Product not requiring special or specific measures subject to compliance with the general industrial hygiene rules.
- **Eye protection:** No special eye protection is recommended under normal conditions of use.
- **Respiratory protection:** No special protection is required provided sufficient ventilation is maintained. If the method for using the product leads to a risk of exposure by inhalation, wear a respirator.
- **Other information:** Do not eat, drink and smoke while using.

BIODEGRADABILITY DATA

IMPREGNATION LIQUID

BIODEGRADABILITY TEST (OECD 301B)

Products in the UMONIUM38® range are easily biodegradable: biodegradability > 60% (81.1%) according to the **OECD 301B test.**

WATER TREATMENT PLANT TESTS

SCAS (Semi-Continuous Activated Sludge) simulation tests performed by analogy with a water treatment station with a treatment capacity of a population equivalent (PE) of 40,000, also showed that concentrated UMONIUM38® is **more than 90% biodegradable.**

WIPE

The wipes are not biodegradable

SAFETY DATA SHEET

The Safety Data Sheet for UMONIUM38® **NEUTRALIS TISSUES** is available on simple request to Laboratoire Huckert's International, via e-mail (**info@huckerts.net**).

laboratoire HUCKERT'S INTERNATIONAL

mastered disinfection

www.huckerts.net

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