SS-032

42.1

MACRODUCT ®
Sweat Collection System

U.S. Patent Number 4,542,751
U.K. Patent Number 2,116,850
Other Patents Pending

ABBREVIATED INSTRUCTIONS FOR USE

DO NOT TOUCH OR OTHERWISE CONTAMINATE
THE CONICAL SURFACE OF MACRODUCT

. Attach the appropriately-sized strap to the MACRODUCT collector with proper orientation for subsequent attachment to limb.

. Thoroughly clean and dry the stimulated skin area.

. Apply the conical surface of MACRODUCT precisely over the stimulated area.

. Fix MACRODUCT very tightly in position using the strap.
MACRODUCT REMAINS ATTACHED DURING STEPS 5 THROUGH 8.

. The protective transparent cover over the spiral microbore tube may be removed by inserting a pointed tool under one of the cut-out sections and prying upward. (The nippers may be conveniently employed for this operation.) It can be removed immediately after attachment of the MACRODUCT unless an elastic bandage or other overwrap is to be used.

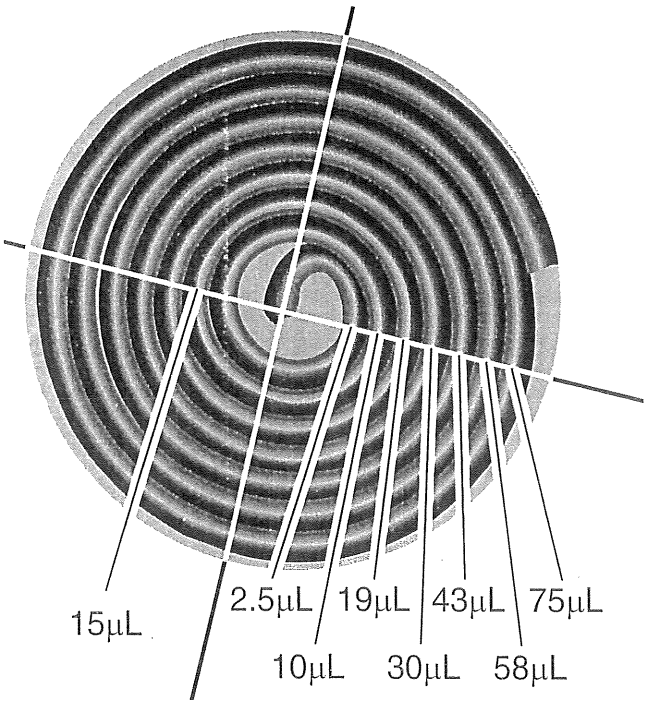
. When sufficient sweat has accumulated,* connect the free end of the microbore tube to the needle of the sweat dispenser or blunt end needle on a syringe. Grasp the end of the microbore tube (not the dispenser or syringe) and carefully lift the tube away from the adhesive surface until its entire length is free.

. Use the nippers to sever the attached end of the microbore tube as closely as possible to the upper surface of the MACRODUCT collector body.

. Immediately transfer the sweat to the sealable microsample cup by gently and continuously squeezing the dispenser to expel the sweat from the microbore tube, or connect the tubing to the nipple of the conductivity cell.

. Remove the MACRODUCT collector body from the patient's limb; retain the attachment strap and discard remainder.

*The bore of the collecting tube is controlled to contain at least 2.7 µL/cm, corresponding to the volumes indicated in the diagram below.



INFORMATION FOR PARENTS:

SWEAT TESTING POSES A REMOTE RISK OF MINOR SKIN BURNS

There is an element of risk inherent in all medical procedures, no matter how simple. The sweat test has been an important laboratory tool since the 1950s. It provides a quantitative test result to confirm or exclude a clinical diagnosis of cystic fibrosis. Unfortunately, the test has been accompanied by occasional minor burns.

The sweat test consists of three sequential procedures: (1) sweat stimulation, (2) sweat collection, and (3) sweat analysis. The first procedure is known as pilocarpine iontophoresis. It is universally accepted by medical authorities as a safe and effective method of stimulating sweat glands. A sweat-inducing drug, pilocarpine, is delivered from the surface of the skin through the watery pathways of the sweat ducts into the sweat glands by a small electric current that is made to flow through the dermal layers. The electric current is supplied by a battery-powered device through a pair of electrodes fitted to the limb of the patient.

Minor skin burns have been an unwelcome, adverse side-effect of pilocarpine iontophoresis from the beginning. Some types of iontophoretic apparatus are prone to cause burns, particularly if there is procedural error. Fortunately, such burns are extremely rare with the Wescor iontophoretic system. It uses a sophisticated microprocessor current controller and a very low delivery current of only 1.5 milliamperes. Pilocarpine is contained in unique Pilogel gel drug reservoirs that are 96% water. These features substantially reduce, but do not totally eliminate, the possibility of skin burns.

Burn descriptions vary from "tiny black pinholes in the skin" to "crater-like, third-degree burns two to three millimeters in diameter." In most of the incidents reported, the children have exhibited no sign of pain or discomfort during iontophoresis, and the burn was not discovered until the electrodes were removed.

Most individuals exhibit a sensitivity to pilocarpine that is typically manifested as mild erythema (redness) of the skin at the electrode locations. In some cases, one or more blister-like welts may also form. These are often mistaken as burns, but they are simply the reaction of the skin to pilocarpine. Such "blisters" invariably disappear within 2 to 3 hours, leaving no after-effects.

Based on current data and reported events, the apparent burn rate is less than 1 in 50,000. Wescor prescribes proper test procedures which minimize the risk of burns from its equipment. It is highly unlikely that your child will suffer a burn during the sweat stimulation phase of the sweat test.

We realize these statistics will be of scant comfort to the parents of a child who has the misfortune of suffering the "one burn in 50,000." However, experience has shown that when burns do occur, the injuries are minor and there are no lasting effects. The burns usually heal completely within one to two weeks with little or no scarring.

WESCOR®
WESCOR, INC
370 West 1700 South, Logan, UT 84321 USA
(435) 752-6011

13 June 2008 PRINT-0028-01 rev B

#44.1

MACRODUCT®
Prakaito rinkimo sistema

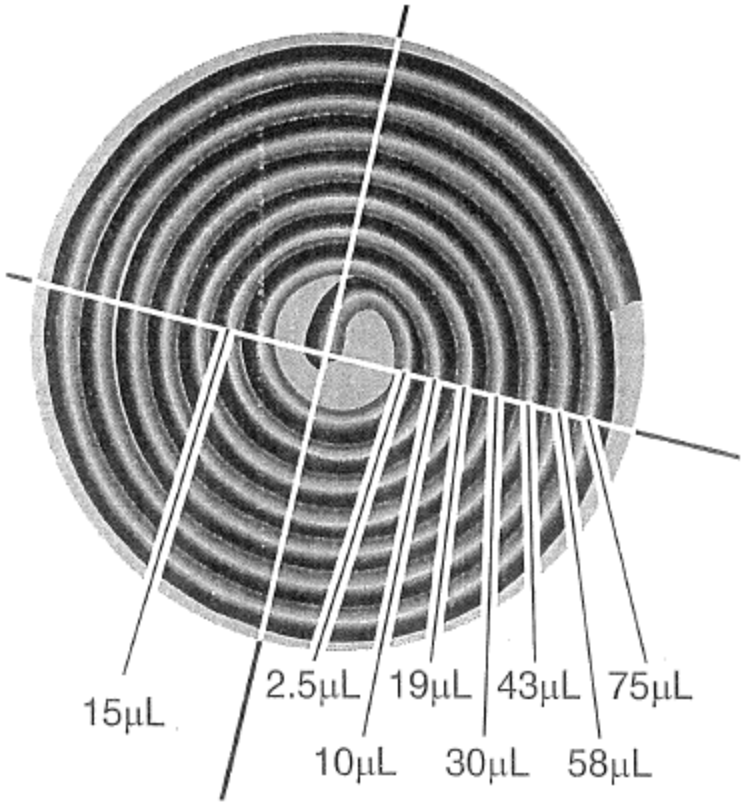
JAV patento Nr. 4,542,751
JAV patento Nr. 2,116,850
Kiti dar negauti patentai

SUTRUMPINTOS NAUDOJIMO INSTRUKCIJOS

NELIESKITE IR KITAIP NEUŽTERŠKITE KŪGINIO MACRODUCT PAVIRŠIAUS

Prijunkite tinkamo dydžio juostelę prie MACRODUCT kolektoriaus, tinkamai nustatę kryptį, kad po to galėtumėte prijungti prie galūnės.
Kruopščiai nuvalykite ir nusausinkite stimuliuojamą odos plotelį.
Uždėkite kūginį MACRODUCT paviršių tiksliai ant stimuliuojamo plotelio.
Labai stipriai užfiksuokite MACRODUCT su juostele.
ATLIEKANT 5-8 VEIKSMUS, MACRODUCT LIEKA PRIJUNGTAS.
Apsauginę permatomą dangą virš spiralinio vamzdelio su mikrodiametru galima nuimti įkišus nusmailintą įrankį po viena iš išpjautų dalių ir spaudžiant į priekį. (Šiam veiksmui patogu naudoti žnyples). Prijungus MACRODUCT, jį galima iš karto išimti, nebent naudosite elastinį bintą ar kitą ant viršaus vyniojamą medžiagą.
Kai susikaupia pakankamai prakaito,* prijunkite laisvą vamzdelio su mikrodiametru galą prie prakaito skirstytuvo adatos ar adatos buku galu ant švirkšto. Suimkite vamzdelio su mikrodiametru galą (ne skirstytuvą ar švirkštą) ir atsargiai kelkite vamzdelį nuo lipnaus paviršiaus, kol visas jo ilgis bus laisvas.
Naudodamiesi žnyplėmis, atskirkite prijungtą vamzdelio su mikrodiametru galą kiek galima arčiau viršutinio MACRODUCT kolektoriaus paviršiaus.
Iš karto supilkite prakaitą į užsandarinamą mikromėginių taurelę, švelniai ir be perstojo spausdami skirstytuvą, kad išstumtumėte prakaitą iš vamzdelio su mikrodiametru, arba prijunkite vamzdelį prie laidumo kameros įmovos.
Nuimkite MACRODUCT kolektorių nuo paciento galūnės; palikite prijungimo juostelę ir išmeskite likutį.

*Surinkimo vamzdelio diametras yra kontroliuojamas taip, kad jame būtų bent 2,7 µl/cm, kas atitinka apatinėje diagramoje pavaizduotus kiekius.



INFORMACIJA PACIENTAMS:

PRAKAITAVIMO TESTAS SUSIJĘS SU NEDIDELE SMULKIŲ ODOS NUDEGIMŲ RIZIKA

Visoms medicininėms procedūroms būdingas rizikos elementas, kad ir kokios paprastos jos būtų. Prakaitavimo testas nuo šeštojo dešimtmečio yra svarbus laboratorinis įrankis. Jis leidžia gauti kiekybinį testo rezultatą, kad būtų galima patvirtinti arba atmesti klinikinę cistinės fibrozės diagnozę. Deja, testas gali būti susijęs su atsitiktiniais smulkiais nudegimais.

Prakaitavimo testą sudaro trys iš eilės einančios procedūros: 1) prakaito stimuliavimas, 2) prakaito surinkimas, 3) prakaito analizė. Pirmoji procedūra žinoma kaip pilokarpino jontoforezė. Medicinos įstaigos ją pripažįsta kaip saugų ir veiksmingą prakaito liaukų stimuliavimo metodą. Prakaitą sukeliantis vaistas pilokarpinas vandeningais prakaito takeliais nuo odos paviršiaus nukeliauja į prakaito liaukas veikiant silpnai elektros srovei, kuri priverčiama tekėti per odos sluoksnius. Elektros srovę tiekia baterija valdomas prietaisas per porą elektrodų, kurie yra sumontuoti ant paciento galūnės.

Smulkūs odos nudegimai nuo pat pradžių buvo nemalonus, neigiamas pilokarpino jontoforezės poveikis. Kai kurie jontoforezės aparatai dažniau sukelia nudegimus, ypač jeigu procedūros metu padaroma klaida. Laimei, tokie nudegimai yra ypač reti naudojant Wescor jontoforezės sistemą. Ją sudaro įmantrus mikroprocesoriaus srovės valdiklis, naudojantis labai silpną, vos 1,5 miliamperų srovę. Pilokarpinas laikomas unikaliose Pilogel gelio vaisto talpyklose, kurių 96 proc. sudaro vanduo. Šios ypatybės reikšmingai sumažina, bet visiškai nepanaikina odos nudegimų tikimybės.

Nudegimų aprašymai skiriasi: nuo „mažyčių juodų smeigtuko galvučių odoje“ iki „panašių į kraterį, dviejų ar trijų milimetrų diametro trečio laipsnio nudegimų“. Daugeliu tų atvejų, kai buvo pranešta apie incidentus, vaikai per jontoforezę nepatyrė skausmo ar diskomforto, o nudegimas nebuvo aptiktas, kol nebuvo nuimti elektrodai.

Daugelis žmonių yra jautrūs pilokarpinui, kas paprastai pasireiškia kaip lengvos formos odos eritema (paraudimas) tose vietose, kur yra elektrodai. Kai kuriais atvejais gali susiformuoti vienas ar du į pūslelę panašūs randeliai. Jie dažnai klaidingai palaikomi nudegimais, bet tai tiesiog odos reakcija į pilokarpiną. Tokios „pūslelės“ visada išnyksta per 2-3 valandas ir nepalieka liekamųjų reiškinių.
Remiantis dabartiniais duomenimis ir pranešamais atvejais, faktinis nudegimų procentas yra mažesnis kaip 1 iš 50000. Wescor nustatė tinkamas testavimo procedūras, kurios iki minimumo sumažina įrangos sukeliamų nudegimų riziką. Nelabai tikėtina, kad jūsų vaikas per prakaito stimuliavimo fazę prakaito testo metu patirs nudegimą.
Mes suvokiame, kad ši statistika nelabai paguos vaiko, kuris turėjo nelaimės patirti „vieną nudegimą iš 50000“, tėvus. Vis dėlto praktika rodo, kad tuomet, kai atsiranda nudegimai, pažeidimai būna smulkūs ir ilgai neišlieka. Nudegimai paprastai užgyja per vieną ar dvi savaites, palikdami tik mažus randelius ar nepalikdami jokių randelių.

WESCOR, INC.
370 West 1700 South, Logan, UT 84321 JAV
(435) 752-6011

2008 metų birželio 13 diena
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459 SOUTH MAIN STREET
LOGAN, UTAH 84321 USA
435 752 6011 ▪ 800 453 2725
FAX 435 752 4127

WESCOR,® INC

DECLARATION
of
CONFORMITY

Manufacturer's Name: Wescor, Inc

Manufacturer's Address: 459 South Main Street
Logan, Utah 84321-5294
USA

declares, the product

Product Name: Macroduct® Sweat Collection System

Model Number: 3700-SYS

Type of Equipment: Battery-powered device used to induce sweat by iontophoresis.

conforms to the applicable sections of the European Union Council Directive concerning medical devices — 93/42/EEC and as a result complies with:

EN55011/CISPR11(1991) (Emissions) RF Emissions Group 1, Class A

EN50082-1(1992) (Immunity)
EN61000-4-2(1991) ESD — 8 kV Air Discharge, 4 kV Contact Discharge
EN61000-4-3(1984) RF Immunity — 3 V/m
and

EN60601-1 (1990) (Safety)

therefore bears the CE Marking as a Class IIA medical device. Certificate issued by Notified Body BSI, 0086.

This declaration applies to the instrument itself and to the accessories and supplies listed hereafter.

Name

Director, QA/RA
Title

6/10/04
Date

Logan, Utah USA
Place

Macroduct Sweat Collection System
Model 3700-SYS

Accessories and Supplies

SS-032	Macroduct Supply Kit (for 6 sweat tests; contains Pilogel® Disc (12 each), Macroduct Sweat Collector (6 each), Small Sealable Container (6 each)).
SS-032-ND	Macroduct Supply Kit, no dye (for 6 sweat tests; contains Pilogel® Disc (12 each), Macroduct Sweat Collector with no dye (6 each), Small Sealable Container (6 each)).
SS-107	Small Sealable Containers (6 each)
SS-128	Macroduct Strap, Small, 14 cm (replaces RP-083)
SS-129	Macroduct Strap, Medium, 18 cm (replaces RP-084)
SS-130	Macroduct Strap, Large, 25 cm (replaces RP-085)
SS-131	Macroduct Strap, Extra Large, 39 cm (replaces RP-086)
SS-132	Macroduct Strap Set (4 straps, 1 of each size; replaces RP-087)
SS-142	Macroduct (collector only, 1 each; replaces SS-042)
SS-142-ND	Macroduct, no dye (collector only, 1 each; replaces SS-042)

MACRODUCT® Supply Kit or Pilogel® Discs

Safety Data Sheet

according to Regulation (EU) 2015/830

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product form	:	Mixture
Product name	:	MACRODUCT® Supply Kit or Pilogel® Discs
Product code	:	SS-032, SS-032G, SS-032IT, SS-032-ND, SS-032G-ND, SS-023, SS-023G, or SS-023IT
Product group	:	Trade product

1.2. Relevant identified uses of the substance or mixture and uses advised against

1.2.1. Relevant identified uses

Industrial/Professional use spec	:	For professional use only
Use of the substance/mixture	:	Sweat Induction for Diagnosis of Cystic Fibrosis

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

ELITechGroup Inc.
370 West 1700 South
84321 Logan, UT - USA
T +1 (435) 752-6011 - F +1 (435) 752-4127
qara_ebs@elitechgroup.com - www.elitechgroup.com

1.4. Emergency telephone number

Emergency number	:	Contact your distributor or poison control center in your country. InfoTrac Emergency Response: Calls within the USA, phone: 1-800-535-5053. Calls outside the USA, phone: +1 352-323-3500 (call collect) Customer ID: #90104 (NOTE: this number is required when a customer calls into either phone number above).

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Acute toxicity (oral) Category 4 H302

Full text of classification categories and H statements : see section 16

2.2. Label elements

Labeling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP) :

GHS07

Signal word (CLP)	:	Warning
Hazardous ingredients	:	Pilocarpine nitrate
Hazard statements (CLP)	:	H302 - Harmful if swallowed
Precautionary statements (CLP)	:	P264 - Wash hands, forearms and face thoroughly after handling P102 - Keep out of reach of children P270 - Do not eat, drink or smoke when using this product P301+P312 - IF SWALLOWED: Call a POISON CENTER, a doctor if you feel unwell P330 - Rinse mouth P501 - Dispose of contents/container to an authorized waste collection point
Security closing plug for children	:	No

Tactile warning : No

2.3. Other hazards

Adverse physicochemical, human health and environmental effects : Harmful if swallowed.

SECTION 3: Composition/Information on ingredients

3.1. Substance

Not applicable

3.2. Mixture

Name	Product identifier	%	Classification according to Directive 67/548/EEC	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Pilocarpine nitrate	(CAS No) 148-72-1	< 1	Not classified	Acute Tox. 2 (Oral), H300 Acute Tox. 2 (Inhalation), H330

Full text of R- and H- phrases: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general : Call a poison center/doctor/physician if you feel unwell.

First-aid measures after inhalation : Remove person to fresh air and keep comfortable for breathing.

First-aid measures after skin contact : Wash skin with plenty of water.

First-aid measures after eye contact : Rinse eyes with water as a precaution.

First-aid measures after ingestion : Rinse mouth. Call a poison center/doctor/physician if you feel unwell.

4.2. Most important symptoms and effects, both acute and delayed

No additional information available

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Water spray. Dry powder. Foam.

5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire : Toxic fumes may be released.

5.3. Advice for firefighters

Protection during firefighting : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Emergency procedures : Ventilate spillage area.

6.1.2. For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Recover mechanically the product.

Other information : Dispose of materials or solid residues at an authorized site.

6.4. Reference to other sections

For further information refer to section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Ensure good ventilation of the work station. Wear personal protective equipment.

Hygiene measures : Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in a well-ventilated place. Keep cool.

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Exposure controls

Appropriate engineering controls : Ensure good ventilation of the work station.

Hand protection : Protective gloves

Environmental exposure controls : Avoid release to the environment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Solid
Color	: Semi-clear; amber
Odor	: characteristic.
Odor threshold	: No data available
pH	: No data available
Relative evaporation rate (butyl acetate=1)	: No data available
Melting point	: No data available
Freezing point	: Not applicable
Boiling point	: > 100 °C
Flash point	: Not applicable
Auto-ignition temperature	: Not applicable
Decomposition temperature	: No data available
Flammability (solid, gas)	: Non flammable
Vapor pressure	: No data available
Relative vapor density at 20 °C	: No data available
Relative density	: Not applicable
Solubility	: Water: No data available
Log Pow	: No data available
Viscosity, kinematic	: Not applicable
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidizing properties	: No data available
Explosion limits	: Not applicable

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

None under recommended storage and handling conditions (see section 7).

10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Oral: Harmful if swallowed.

ATE CLP (oral)	1046 mg/kg body weight

Pilocarpine nitrate (148-72-1)	
LD50 oral rat	911 mg/kg

Skin corrosion/irritation : Not classified

Serious eye damage/irritation : Not classified

Respiratory or skin sensitization : Not classified

Germ cell mutagenicity : Not classified

Carcinogenicity : Not classified

Reproductive toxicity : Not classified

Specific target organ toxicity (single exposure) : Not classified

Specific target organ toxicity (repeated exposure) : Not classified

Aspiration hazard : Not classified

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : The product is not considered harmful to aquatic organisms or to cause long-term adverse effects in the environment.

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

No additional information available

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste treatment methods : Dispose of contents/container in accordance with licensed collector's sorting instructions.

SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

14.1. UN number

Not regulated for transport

14.2. UN proper shipping name

Proper Shipping Name (ADR) : Not applicable
Proper Shipping Name (IMDG) : Not applicable
Proper Shipping Name (IATA) : Not applicable
Proper Shipping Name (ADN) : Not applicable
Proper Shipping Name (RID) : Not applicable

14.3. Transport hazard class(es)

ADR

Transport hazard class(es) (ADR) : Not applicable

IMDG

Transport hazard class(es) (IMDG) : Not applicable

IATA

Transport hazard class(es) (IATA) : Not applicable

ADN

Transport hazard class(es) (ADN) : Not applicable

RID

Transport hazard class(es) (RID) : Not applicable

14.4. Packing group

Packing group (ADR) : Not applicable
Packing group (IMDG) : Not applicable
Packing group (IATA) : Not applicable
Packing group (ADN) : Not applicable
Packing group (RID) : Not applicable

14.5. Environmental hazards

Dangerous for the environment : No
Marine pollutant : No
Other information : No supplementary information available

14.6. Special precautions for user

- Overland transport

No data available

- Transport by sea

No data available

- Air transport

No data available

- Inland waterway transport

No data available

- Rail transport

No data available

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

15.1.1. EU-Regulations

Contains no REACH substances with Annex XVII restrictions

Contains no REACH candidate substance

Contains no REACH Annex XIV substances.

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Full text of R-, H- and EUH-phrases:

Acute Tox. 2 (Inhalation)	Acute toxicity (inhalation) Category 2
Acute Tox. 2 (Oral)	Acute toxicity (oral) Category 2
Acute Tox. 4 (Oral)	Acute toxicity (oral) Category 4
H300	Fatal if swallowed
H302	Harmful if swallowed
H330	Fatal if inhaled

SDS EU Custom - EBS

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

Reason for change: Format change to meet GHS compliance.

1 SKIRSNIS. Cheminės medžiagos ir (arba) mišinio ir bendrovės ir (arba) įmonės identifikavimas

1.1 Produkto identifikatorius

Produkto forma:	mišinys
Produkto pavadinimas:	MACRODUCT® tiekimo rinkinys arba Pilogel® diskai
Produkto kodas:	SS-032, SS-03G, SS-032IT, SS-032-ND, SS-032G-ND, SS-023, SS-023G arba SS-023IT
Produkto grupė:	prekybinis produktas

1.2 Medžiagos ar mišinio nustatyti naudojimo būdai ir nerekomenduojami naudojimo būdai

1.2.1 Rekomenduojami naudojimo būdai:

Pramoninio/profesionalaus naudojimo specifikacija:	tik profesionaliam naudojimui
Medžiagos/mišinio naudojimas:	prakaito indukcijas diagnozuojant cistinę fibrozę

1.2.2 Nerekomenduojami naudojimo būdai:

Papildomos informacijos nėra.

1.3 Išsami informacija apie produkto ir saugos duomenų lapo tiekėją

Gamintojas:
ELITechGroup Inc.
370 West 1700 South
Logan, UT 84321 - JAV
T +1 (435) 752-6011 - F +1 (435) 752-4127
qara_ebs@elitechgroup.com - www.elitechgroup.com

Tiekėjas:
UAB „Interlux“, Aviečių g. 16, LT-08418 Vilnius, Lietuva
Tel.: +370 5 2786850, faks.: +370 5 2796728, www.interlux.lt.
Už saugos duomenų lapą atsakingo asmens el. pašto adresas: spirit@interlux.lt

1.4 Pagalbos telefono numeris

Apsinuodijimų kontrolės ir informacijos biuras (visą parą): tel. +370 52 362052, mob. +370 687 53378. Bendras pagalbos telefonas – 112.

2 SKIRSNIS. Galimi pavojai

2.1 Medžiagos arba mišinio klasifikavimas

Klasifikacija pagal (EB) reglamentą nr. 1272/2008 [CLP]

Ūmus toksiškumas (prarijus), 4 pav. kat.	H302

Pilnas pavojingumo klasių ir frazių tekstas pateikiamas 16 skirsnyje.

2.2 Ženklinimo elementai

Ženklinimas pagal (EB) reglamentą nr. 1272/2008 [CLP]

Pavojaus piktogramos (CLP)

Signalinis žodis (CLP): Atsargiai

Pavojingos sudedamosios dalys: pilokarpino nitratas
Pavojingumo frazė(s) (CLP):
H302: Kenksminga prarijus.
Atsargumo frazė(s) (CLP):
P264: Po naudojimo kruopščiai nuplauti
P102: Laikyti vaikams neprieinamoje vietoje.
P270: Naudojant šį produktą, nevalgyti, negerti ir nerūkyti.
P301+P312: PRARIJUS: Pasijutus blogai, skambinti į APSINUODIJIMŲ KONTROLĖS IR INFORMACIJOS BIURĄ arba kreiptis į gydytoją.
P330: Išskalauti burną.
P501: Turinį/talpyklą išmesti įgaliotoje atliekų surinkimo vietoje.

Apsauginis kaištis nuo vaikų: nėra
Apčiuopiamasis įspėjimas: nėra

2.3 Kiti pavojai
Šalutinis fizikocheminis poveikis, poveikiai žmogaus sveikatai ir aplinkai: kenksminga prarijus.

3 SKIRSNIS. Sudėtis/informacija apie komponentus
3.1 Su medžiaga susijusi informacija
Netaikoma

3.2 Su mišiniu susijusi informacija

Pavadinimas	Produkto identifikatorius	%	Klasifikacija pagal direktyvą 67/548/EEB	Klasifikacija pagal (EB) reglamentą nr. 1272/2008 [CLP]
pilokarpino nitratas	(CAS nr.) 148-72-1	<1	Neklasifikuojama	Ūmus toksiškumas prarijus, 2 pav. kat., H330 Ūmus toksiškumas įkvėpus, 2 pav. kat., H330

Pilnas H-frazių ir R-frazių, paminėtų šiame skirsnyje, tekstas pateikiamas 16 skirsnyje.

4 SKIRSNIS. Pirmosios pagalbos priemonės
4.1 Pirmosios pagalbos priemonių aprašymas
Bendra rekomendacija: Jeigu asmuo jaučiasi blogai, kreipkitės į apsinuodijimo centrą/gydytojus.
Įkvėpus: leiskite nukentėjusiajam kvėpuoti gryną orą. Leiskite nukentėjusiajam ilsėtis.
Patekus ant odos: plauti gausiu kiekiu vandens.
Patekus į akis: plaukite akis vandeniu.
Nurijus: skalaukite burną. Jeigu asmuo jaučiasi blogai, kreipkitės į apsinuodijimo centrą/gydytojus.

4.2 Svarbiausi simptomai ir poveikis (ūmus ir uždelstas)
Kitos papildomos informacijos nėra.

4.3 Nurodymas apie bet kokios neatidėliotinos medicinos pagalbos ir specialaus gydymo reikalingumą
Gydyti pagal simptomus.

5 SKIRSNIS. Priešgaisrinės priemonės
5.1 Gesinimo priemonės
Tinkamos gesinimo priemonės: vandens čiurkšlė. Sausi milteliai. Putos.

5.2 Specialūs medžiagos arba mišinio keliami pavojai
Pavojingi skilimo produktai gaisro metu: gali išsiskirti toksiški dūmai.

5.3 Patarimai gaisrininkams
Apsauga gaisro gesinimo metu: nebandykite imtis jokių veiksmų be tinkamos apsauginės įrangos. Savaiminis kvėpavimo prietaisas. Pilna apsauginė apranga.

6 SKIRSNIS. Avarijų likvidavimo priemonės
6.1 Asmens atsargumo priemonės, apsaugos priemonės ir skubios pagalbos procedūros
6.1.1 Ne skubios pagalbos personalui
Skubios pagalbos procedūros: ventiliuokite išsiliejimo vietą.

6.1.2 Skubios pagalbos personalui
Apsauginė įranga: nebandykite imtis jokių veiksmų be tinkamos apsauginės įrangos. Daugiau informacijos rasite 8 skirsnyje Poveikio prevencija/asmens apsauga.

6.2 Ekologinės atsargumo priemonės
Venkite patekimo į aplinką.

6.3 Izoliavimo ir valymo procedūros bei priemonės
Valymo metodai: produktą surinkite mechaniškai.
Kita informacija: medžiagas arba kietas liekanas utilizuokite įgaliotoje įstaigoje.

6.4 Papildoma informacija
Žr. 13 skirsnį.

7 SKIRSNIS. Naudojimas ir sandėliavimas
7.1 Su saugiu tvarkymu susijusios atsargumo priemonės
Su saugiu tvarkymu susijusios atsargumo priemonės: darbo vietoje užtikrinkite tinkamą ventiliaciją. Dėvėkite asmeninės apsaugos įrangą.
Higienos priemonės: dirbdami su produktu nevalgykite, negerkite ar nerūkykite. Visada po darbo su produktu plaukite rankas.

7.2 Saugaus sandėliavimo sąlygos, įskaitant visus nesuderinamumus
Sandėliavimo sąlygos: sandėliuoti gerai ventiliuojamoje vietoje. Laikyti vėsioje vietoje.

7.3 Konkretus (-ūs) galutinio naudojimo būdas (-ai)
Papildomos informacijos nėra.

8 SKIRSNIS. Poveikio prevencija/asmens apsauga
8.1 Kontrolės parametrai
Papildomos informacijos nėra.

8.2 Poveikio kontrolė

Tinkamos inžinerinės kontrolės:	darbo vietoje užtikrinkite tinkamą ventiliaciją.
Rankų apsauga:	apsauginės pirštinės.
Aplinkos poveikio kontrolės:	venkite patekimo į aplinką.

9 SKIRSNIS. Fizinės ir cheminės savybės
9.1 Informacija apie pagrindines fizines ir chemines savybes

Fizinė būsena:	Kieta
Spalva:	Pusiau skaidri; gintaro
Kvapas:	Būdingas

Kvapo atsiradimo riba:	Duomenų nėra
pH:	Duomenų nėra
Santykinis garavimo greitis (butilacetatas – 1):	Duomenų nėra
Lydymosi temperatūra:	Duomenų nėra
Užšalimo temperatūra:	Netaikoma
Virimo temperatūra:	>100^{0}C
Pliūpsnio temperatūra:	Netaikoma
Savaiminio užsidegimo temperatūra:	Netaikoma
Skilimo temperatūra:	Duomenų nėra
Degumas (kietos, dujinės būsenos):	Nedegus
Garų slėgis:	Duomenų nėra
Santykinis garų tankis esant 20^{0}C:	Duomenų nėra
Santykinis tankis:	Netaikomas
Tirpumas:	Vandenyje: duomenų nėra
Log Pow:	Duomenų nėra
Klampumas, kinematinis:	Netaikomas
Klampumas, dinaminis:	Duomenų nėra
Sprogimo ypatybės:	Duomenų nėra
Oksiduojančios ypatybės:	Duomenų nėra
Sprogimo ribos:	Netiakoms

9.2 Kita informacija
Kitos papildomos informacijos nėra.

10 SKIRSNIS. Stabilumas ir reaktingumas
10.1 Reaktingumas
Esant įprastoms naudojimo, sandėliavimo ir transportavimo sąlygoms produktas nėra reaktyvus.

10.2 Cheminis stabilumas
Stabilus esant įprastoms sąlygoms.

10.3 Pavojingų reakcijų galimybė
Pavojingos reakcijos nėra žinomos, kai produktas naudojamas įprastai.

10.4 Vengtinos sąlygos
Pagal nurodytas tvarkymo ir sandėliavimo sąlygas nėra (žr. 7 skirsnį).

10.5 Nesuderinamos medžiagos
Kitos papildomos informacijos nėra.

10.6 Pavojingi skilimo produktai
Esant įprastoms naudojimo, sandėliavimo sąlygoms, pavojingi skilimo produktai neišsiskiria.

11 SKIRSNIS. Toksikologinė informacija

11.1 Informacija apie toksinį poveikį
Ūmus toksiškumas: prarijus: kenksminga prarijus.

ATE CLP (prarijus)	1046 mg/kg kūno svorio

pilokarpino nitratas (148-72-1)	
LD50 oralinis, žiurkė	911 mg/kg

Odos ėsdinimas/dirginimas:	neklasifikuojamas.
Smarkus akių pažeidimas/dirginimas:	neklasifikuojamas.
Kvėpavimo takų arba odos jautrinimas:	neklasifikuojamas.
Lytinių ląstelių mutageniškumas:	neklasifikuojamas.
Kancerogeniškumas:	neklasifikuojamas.
Toksiškumas reprodukcijai:	neklasifikuojamas.
Specifinis toksiškumas konkrečiam organui (vienkartinis poveikis)	neklasifikuojamas.
Specifinis toksiškumas konkrečiam organui (kartotinis poveikis)	neklasifikuojamas.
Aspiracijos pavojus	neklasifikuojamas.

12 SKIRSNIS. Ekologinė informacija

12.1 Ekotoksiškumas

Ekologija-bendrai: produktas nėra laikomas pavojingu vandens organizmams arba galintis sukelti ilgalaikius šalutinius poveikius aplinkai.

12.2 Patvarumas ir skaidomumas

Kitos papildomos informacijos nėra.

12.3 Bioakumuliacijos potencialas

Kitos papildomos informacijos nėra.

12.4 Judrumas dirvožemyje

Kitos papildomos informacijos nėra.

12.5 PBT ir vPvB vertinimo rezultatai

Kitos papildomos informacijos nėra.

12.6 Kitas nepageidaujamas poveikis

Kitos papildomos informacijos nėra.

13 SKIRSNIS. Atliekų tvarkymas

13.1 Atliekų tvarkymo metodai

Atliekų tvarkymo metodai: utilizuokite saugiu būdu pagal licencijuotos surinkimo įstaigos rūšiavimo instrukcijas.

14 SKIRSNIS. Informacija apie gabenimą

Pagal ADR/RID/IMDG/IATA/ADN

14.1 JT nr.

Transportavimas nereguliuojamas.

14.2 JT teisingas krovinio pavadinimas

Teisingas krovinio pavadinimas (ADR):	netaikomas
Teisingas krovinio pavadinimas (IMDG):	netaikomas
Teisingas krovinio pavadinimas (IATA):	netaikomas
Teisingas krovinio pavadinimas (ADN):	netaikomas
Teisingas krovinio pavadinimas (RID):	netaikomas

14.3 Transporto pavojaus klasė(s)

ADR

Transporto pavojingo klasė(s) (ADR):	netaikomas

IMDG

Transporto pavojingo klasė(s) (IMDG):	netaikomas

IATA

Transporto pavojingo klasė(s) (IATA):	netaikomas

ADN

Transporto pavojingo klasė(s) (ADN):	netaikomas

RID

Transporto pavojingo klasė(s) (RID):	netaikomas

14.4 Pakuotės grupė

Pakuotės grupė (ADR):	Netaikomas
Pakuotės grupė (IMDG):	Netaikomas
Pakuotės grupė (IATA):	Netaikomas
Pakuotės grupė (ADN):	Netaikomas
Pakuotės grupė (RID):	Netaikomas

14.5 Pavojai aplinkai

Pavojinga aplinkai:	Ne
Jūrų teršalas:	Ne
Kita informacija:	kitos papildomos informacijos nėra

14.6 Specialios atsargumo priemonės vartotojams

Transportavimui žeme

Duomenų nėra

Transportavimui jūra

Duomenų nėra

Transportavimui oru

Duomenų nėra

Transportavimui vidaus vandenyse

Duomenų nėra.

Transportavimui geležinkeliais

Duomenų nėra.

14.7 Nesupakuotų krovinių transportavimas pagal MARPOL 73/78 II priedą ir IBC kodą

Netaikoma.

15 SKIRSNIS. Informacija apie reglamentavimą

15.1 Su konkrečia medžiaga ar mišiniu susiję saugos, sveikatos ir aplinkos teisės aktai

- Pagal „Europos Parlamento ir Tarybos reglamentą (EB) Nr. 1272/2008 dėl cheminių medžiagų

ir mišinių klasifikavimo, ženklinimo ir pakavimo, kuris iš dalies keičia ir panaikina direktyvas 67/548/EEB bei 1999/45/EB ir iš dalies keičia Reglamentą (EB) Nr. 1907/2006“, yra paskelbtas Europos Sąjungos oficialiajame leidinyje Nr. L353, 51 tomas, 2008 m. gruodžio 31 d.;
- Europos Parlamento ir Tarybos reglamentas (EB) Nr. 1907/2006 dėl cheminių medžiagų registracijos, įvertinimo, autorizacijos ir apribojimų (REACH);
- KOMISIJOS REGLAMENTAS (ES) Nr. 453/2010 iš dalies keičiantis Europos Parlamento ir Tarybos reglamentą (EB) Nr. 1907/2006 dėl cheminių medžiagų registracijos, įvertinimo, autorizacijos ir apribojimų (REACH);
-Pagal HN 23 „Cheminių medžiagų profesinio poveikio ribiniai dydžiai. Matavimo ir poveikio vertinimo bendrieji reikalavimai”;
-Pagal HN 36 „Draudžiamos ir ribojamos medžiagos“;
-Pagal galiojančius „Darbuotojų apsaugos nuo cheminių veiksnių darbe nuostatus” ir „Darbuotojų apsaugos nuo kancerogenų ir mutagenų poveikio darbe nuostatus“;
- Pagal galiojantį „Lietuvos Respublikos atliekų tvarkymo įstatymą“;
- Pagal galiojantį „Lietuvos Respublikos pakuočių ir pakuočių atliekų tvarkymo įstatymą“;
- Pagal galiojančias „Atliekų tvarkymo taisykles“.

15.2 Cheminės saugos vertinimas
Pagal REACH cheminės saugos ataskaita nereikalinga.

16 SKIRSNIS. Kita informacija

Pilnas R-, H- ir EUH- frazių tekstas:

H300	Mirtina prarijus.
H302	Kenksminga prarijus.
H330	Mirtina įkvėpus.

Ši informacija yra paremta esamomis mūsų žiniomis ir skirta apibūdinti produktą sveikatos, saugos ir aplinkos reikalavimų tikslais. Todėl ji nėra laikoma garantija bet kokioms specifinės produkto savybėms.

Keitimo priežastis: Formato keitimas GHS atitikčiai.

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product form : Mixture

Trade name : CALIBRATOR for Sweat-Chek™

Product code : SS-140

Product group : Trade product

#44.2

1.2. Relevant identified uses of the substance or mixture and uses advised against

1.2.1. Relevant identified uses

Industrial/Professional use spec : For professional use only

Use of the substance/mixture : Sodium Chloride Solution, Saline

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

ELITechGroup Inc.
370 West 1700 South
84321 Logan, UT - USA
T +1 (435) 752-6011 - F +1 (435) 752-4127
qara_ebs@elitechgroup.com - www.elitechgroup.com

1.4. Emergency telephone number

Emergency number : Contact your distributor or poison control center in your country.
InfoTrac Emergency Response: Calls within the USA, phone: 1-800-535-5053. Calls outside the USA, phone: +1 352-323-3500 (call collect)
Customer ID: #90104 (NOTE: this number is required when a customer calls into either phone number above).

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Not classified

2.2. Label elements

Labeling according to Regulation (EC) No. 1272/2008 [CLP]

Security closing plug for children : No

Tactile warning : No

2.3. Other hazards

No additional information available

SECTION 3: Composition/Information on ingredients

3.1. Substance

Not applicable

3.2. Mixture

This mixture does not contain any substances to be mentioned according to the criteria of section 3.2 of REACH annex II

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general : Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

First-aid measures after inhalation : Allow victim to breathe fresh air. Allow the victim to rest.

First-aid measures after skin contact : Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse.

First-aid measures after eye contact : Rinse immediately with plenty of water. Obtain medical attention if pain, blinking or redness persist.

First-aid measures after ingestion : Rinse mouth. Do NOT induce vomiting. Obtain emergency medical attention.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms/injuries : Not expected to present a significant hazard under anticipated conditions of normal use.

4.3. Indication of any immediate medical attention and special treatment needed

No additional information available

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Foam. Dry powder. Carbon dioxide. Water spray. Sand.

Unsuitable extinguishing media : Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

No additional information available

5.3. Advice for firefighters

Firefighting instructions : Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent fire-fighting water from entering environment.

Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Emergency procedures : Evacuate unnecessary personnel.

6.1.2. For emergency responders

Protective equipment : Equip cleanup crew with proper protection.

Emergency procedures : Ventilate area.

6.2. Environmental precautions

No additional information available

6.3. Methods and material for containment and cleaning up

No additional information available

6.4. Reference to other sections

See Heading 8. Exposure controls and personal protection.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work.

7.2. Conditions for safe storage, including any incompatibilities

Incompatible products : Strong bases. Strong acids.

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Exposure controls

Personal protective equipment : Avoid all unnecessary exposure.

Other information : Do not eat, drink or smoke during use.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Color	: Colorless.
Odor	: characteristic.
Odor threshold	: No data available
pH	: No data available
Relative evaporation rate (butyl acetate=1)	: No data available
Melting point	: No data available
Freezing point	: No data available
Boiling point	: 100 °C
Flash point	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: Non flammable
Vapor pressure	: No data available
Relative vapor density at 20 °C	: No data available
Relative density	: No data available
Solubility	: Water: No available data
Log Pow	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidizing properties	: No data available
Explosion limits	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No additional information available

10.2. Chemical stability

Not established.

10.3. Possibility of hazardous reactions

Not established.

10.4. Conditions to avoid

No additional information available

10.5. Incompatible materials

Strong acids. Strong bases.

10.6. Hazardous decomposition products

No additional information available

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Not classified

Skin corrosion/irritation : Not classified
Based on available data, the classification criteria are not met

Serious eye damage/irritation : Not classified
Based on available data, the classification criteria are not met

Respiratory or skin sensitization : Not classified
Based on available data, the classification criteria are not met

Germ cell mutagenicity : Not classified
Based on available data, the classification criteria are not met

Carcinogenicity : Not classified
Based on available data, the classification criteria are not met

Reproductive toxicity : Not classified
Based on available data, the classification criteria are not met

Specific target organ toxicity (single exposure) : Not classified
Based on available data, the classification criteria are not met

Specific target organ toxicity (repeated exposure) : Not classified
Based on available data, the classification criteria are not met

Aspiration hazard : Not classified
Based on available data, the classification criteria are not met

Potential Adverse human health effects and symptoms : Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

12.1. Toxicity

No additional information available

12.2. Persistence and degradability

CALIBRATOR for Sweat-Chek	
Persistence and degradability	Not established.

12.3. Bioaccumulative potential

CALIBRATOR for Sweat-Chek	
Bioaccumulative potential	Not established.

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Other adverse effects

Additional information : Avoid release to the environment

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste disposal recommendations : Dispose in a safe manner in accordance with local/national regulations.

SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

14.1. UN number

Not regulated for transport

14.2. UN proper shipping name

Proper Shipping Name (ADR)	:	Not applicable
Proper Shipping Name (IMDG)	:	Not applicable
Proper Shipping Name (IATA)	:	Not applicable
Proper Shipping Name (ADN)	:	Not applicable
Proper Shipping Name (RID)	:	Not applicable

14.3. Transport hazard class(es)

ADR

Transport hazard class(es) (ADR)	:	Not applicable

IMDG

Transport hazard class(es) (IMDG)	:	Not applicable

IATA

Transport hazard class(es) (IATA)	:	Not applicable

ADN

Transport hazard class(es) (ADN)	:	Not applicable

RID

Transport hazard class(es) (RID)	:	Not applicable

14.4. Packing group

Packing group (ADR)	:	Not applicable
Packing group (IMDG)	:	Not applicable
Packing group (IATA)	:	Not applicable
Packing group (ADN)	:	Not applicable
Packing group (RID)	:	Not applicable

14.5. Environmental hazards

Dangerous for the environment	:	No
Marine pollutant	:	No
Other information	:	No supplementary information available

14.6. Special precautions for user

- Overland transport

No data available

- Transport by sea

No data available

- Air transport

No data available

- Inland waterway transport

No data available

- Rail transport

No data available

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

15.1.1. EU-Regulations

Contains no REACH substances with Annex XVII restrictions

Contains no REACH candidate substance

Contains no REACH Annex XIV substances.

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Other information : None.

SDS EU Custom - EBS

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

Reason for change: Format change to meet GHS compliance.

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product form	:	Mixture
Product name	:	Sweat Controls for Cystic Fibrosis Testing
Product code	:	SS-150
Product group	:	Trade product

#44.3

1.2. Relevant identified uses of the substance or mixture and uses advised against

1.2.1. Relevant identified uses

Industrial/Professional use spec	:	For professional use only
Use of the substance/mixture	:	Sodium and Chloride in Simulated Human Sweat Matrix. Sweat Control Levels: 1, 2, and 3.

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

ELITechGroup Inc.
370 West 1700 South
84321 Logan, UT - USA
T +1 (435) 752-6011 - F +1 (435) 752-4127
qara_ebs@elitechgroup.com - www.elitechgroup.com

1.4. Emergency telephone number

Emergency number	:	Contact your distributor or poison control center in your country. InfoTrac Emergency Response: Calls within the USA, phone: 1-800-535-5053. Calls outside the USA, phone: +1 352-323-3500 (call collect) Customer ID: #90104 (NOTE: this number is required when a customer calls into either phone number above).

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Hazardous to the aquatic environment - Chronic Hazard Category 3 H412

Full text of classification categories and H statements : see section 16

2.2. Label elements

Labeling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP) :

GHS07

Signal word (CLP)	:	Warning
Hazard statements (CLP)	:	H317 - May cause an allergic skin reaction H412 - Harmful to aquatic life with long lasting effects
Precautionary statements (CLP)	:	P273 - Avoid release to the environment P302+P352 - IF ON SKIN: Wash with plenty of water
EUH phrases	:	EUH208 - Contains METHYLCHLOROISOTHIAZOLINONE(26172-55-4), METHYLISOTHIAZOLINONE(2682-20-4). May produce an allergic reaction
Security closing plug for children	:	No
Tactile warning	:	No

2.3. Other hazards

Adverse physicochemical, human health and environmental effects : To our knowledge, this product does not present any particular risk, provided it is handled in accordance with good occupational hygiene and safety practice.

SECTION 3: Composition/Information on ingredients

3.1. Substance

Not applicable

3.2. Mixture

Name	Product identifier	%	GHS-US classification
5-chloro-2-methyl-2H-isothiazol-3-one	(CAS No) 26172-55-4 (EC Number) 247-500-7	< 0.5	Acute Tox. 3 (Oral), H301 Acute Tox. 3 (Dermal), H311 Skin Corr. 1B, H314 Eye Dam. 1, H318 Skin Sens. 1, H317 STOT SE 3, H335 Aquatic Acute 1, H400
2-methyl-2H-isothiazol-3-one	(CAS No) 2682-20-4 (EC Number) 220-239-6	< 0.5	Acute Tox. 3 (Oral), H301 Acute Tox. 3 (Dermal), H311 Skin Corr. 1B, H314 Eye Dam. 1, H318 Skin Sens. 1, H317 STOT SE 3, H335 Aquatic Acute 1, H400

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures after inhalation : Remove person to fresh air and keep comfortable for breathing.

First-aid measures after skin contact : Wash skin with plenty of water.

First-aid measures after eye contact : Rinse eyes with water as a precaution.

First-aid measures after ingestion : Call a poison center/doctor/physician if you feel unwell.

4.2. Most important symptoms and effects, both acute and delayed

No additional information available

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Water spray. Dry powder. Foam. Carbon dioxide.

5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire : Toxic fumes may be released.

5.3. Advice for firefighters

Protection during firefighting : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Emergency procedures : Ventilate spillage area.

6.1.2. For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Take up liquid spill into absorbent material.

Other information : Dispose of materials or solid residues at an authorized site.

6.4. Reference to other sections

For further information refer to section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Ensure good ventilation of the work station. Wear personal protective equipment.

Hygiene measures : Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in a well-ventilated place. Keep cool.

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Exposure controls

Appropriate engineering controls : Ensure good ventilation of the work station.

Hand protection : Protective gloves

Environmental exposure controls : Avoid release to the environment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Color	: No data available
Odor	: No data available
Odor threshold	: No data available
pH	: No data available
Relative evaporation rate (butyl acetate=1)	: No data available
Melting point	: Not applicable
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: Not applicable
Vapor pressure	: No data available
Relative vapor density at 20 °C	: No data available
Relative density	: No data available
Solubility	: Water: No data available
Log Pow	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidizing properties	: No data available

Explosion limits : No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

None under recommended storage and handling conditions (see section 7).

10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Not classified

5-chloro-2-methyl-2H-isothiazol-3-one (2682-20-4)	
ATE US (oral)	100.000 mg/kg body weight
ATE US (dermal)	300.000 mg/kg body weight

2-methyl-2H-isothiazol-3-one (26172-55-4)	
ATE US (oral)	100.000 mg/kg body weight
ATE US (dermal)	300.000 mg/kg body weight

Skin corrosion/irritation : Not classified

Serious eye damage/irritation : Not classified

Respiratory or skin sensitization : Not classified

Germ cell mutagenicity : Not classified

Carcinogenicity : Not classified

Reproductive toxicity : Not classified

Specific target organ toxicity (single exposure) : Not classified

Specific target organ toxicity (repeated exposure) : Not classified

Aspiration hazard : Not classified

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : The product is not considered harmful to aquatic organisms or to cause long-term adverse effects in the environment.

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

No additional information available

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste treatment methods : Dispose of contents/container in accordance with licensed collector's sorting instructions.

SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

14.1. UN number

Not regulated for transport

14.2. UN proper shipping name

Proper Shipping Name (ADR) : Not applicable
Proper Shipping Name (IMDG) : Not applicable
Proper Shipping Name (IATA) : Not applicable
Proper Shipping Name (ADN) : Not applicable
Proper Shipping Name (RID) : Not applicable

14.3. Transport hazard class(es)

ADR

Transport hazard class(es) (ADR) : Not applicable

IMDG

Transport hazard class(es) (IMDG) : Not applicable

IATA

Transport hazard class(es) (IATA) : Not applicable

ADN

Transport hazard class(es) (ADN) : Not applicable

RID

Transport hazard class(es) (RID) : Not applicable

14.4. Packing group

Packing group (ADR) : Not applicable
Packing group (IMDG) : Not applicable
Packing group (IATA) : Not applicable
Packing group (ADN) : Not applicable
Packing group (RID) : Not applicable

14.5. Environmental hazards

Dangerous for the environment : No
Marine pollutant : No
Other information : No supplementary information available

14.6. Special precautions for user

- Overland transport

No data available

- Transport by sea

No data available

- Air transport

No data available

- Inland waterway transport

No data available

- Rail transport

No data available

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

15.1.1. EU-Regulations

Contains no REACH substances with Annex XVII restrictions

Contains no REACH candidate substance

Contains no REACH Annex XIV substances.

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Full text of H-phrases:

Acute Tox. 3 (Dermal)	Acute toxicity (dermal) Category 3
Acute Tox. 3 (Oral)	Acute toxicity (oral) Category 3
Aquatic Acute 1	Hazardous to the aquatic environment - Acute Hazard Category 1
Eye Dam. 1	Serious eye damage/eye irritation Category 1
Skin Corr. 1B	Skin corrosion/irritation Category 1B
Skin Sens. 1	Skin sensitization Category 1
STOT SE 3	Specific target organ toxicity (single exposure) Category 3
H301	Toxic if swallowed
H311	Toxic in contact with skin
H314	Causes severe skin burns and eye damage
H317	May cause an allergic skin reaction
H318	Causes serious eye damage
H335	May cause respiratory irritation
H400	Very toxic to aquatic life

SDS EU Custom – EBS

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

Reason for change: Format change to meet GHS compliance.

#42.2

WESCOR®

GLASS ENCAPSULATED CALIBRATOR SOLUTION
FOR SWEAT-CHEK™ CONDUCTIVITY ANALYZER
For In Vitro Diagnostic Use

Intended Use

Wescor's CALIBRATOR solution is for calibration of the Sweat-Chek Sweat Conductivity Analyzer.

Product Description

Wescor's CALIBRATOR solution is liquid, ready to use, and requires no reconstitution or dilution. Each ampule contains 0.75 mL of NaCl solution, at 90 mmol/L molarity.

Warnings and Precautions

No special precautions are required in handling the product other than those routinely used in the laboratory.

Storage and Stability

1. CALIBRATOR should be stored at room temperature.
2. Each ampule contains 0.75 mL of solution. This volume adequately mitigates evaporative concentration for a few hours after the ampule is broken. Ampules are intended for one-time use only.

Instructions for Use

1. Invert gently to ensure homogeniety of the contents.
2. Before opening, flip the neck of the ampule or tap the ampule bottom against a hard surface to clear solution from the neck.
3. Place the ampule in the ampule breaking position of the organizer.
4. Place the safety sleeve over the neck of the ampule.
5. Holding ampule organizer down against the counter, grasp the neck of the ampule firmly between thumb and forefinger and snap the neck off.
6. Sample directly from the ampule, using a fresh Sweat-Chek take up tube to avoid contamination of the solution.
7. Follow procedures in User's Manual to assay CALIBRATOR solution.

Expected Values

The Sweat-Chek conductivity cell has an extremely stable response characteristic that is virtually linear through the critical range from 75 to 110 mmol/L. The main purpose of calibration is to ascertain that the conductivity cell temperature is within the correct range and that the electronics are otherwise functioning normally. If the conductivity cell is free of residual salt or water, a reading within ± 2 of the labeled value of 90 mmol/L indicates overall performance to a very high level of confidence. If the reading falls outside of this range, follow the instructions listed in the User's Manual for calibrating the instrument.

Catalog Number SS-140

Wescor, Inc
459 South Main Street, Logan, Utah 84321
USA
800 453 2725
435 752 6011
Fax: 435 752 4127

IS20A46

#44.2

Į STIKLINĘ KAPSULĘ PATALPINTAS KALIBRATORIAUS TIRPALAS, SKIRTAS SWEAT-CHEK™ SAVITOJO LAIDUMO ANALIZATORIUI
In vitro diagnostiniam naudojimui

Numatytas naudojimas
Wescor KALIBRATORIAUS tirpalas yra skirtas Sweat-Check prakaito savitojo laidumo analizatoriaus kalibravimui.

Produkto apibūdinimas
Wescor KALIBRATORIAUS tirpalas yra paruoštas naudoti skystis, kuriam papildomas skiedimas ar tirpinimas nėra reikalingas. Kiekviena ampulė turi 0.75 mL NaCl tirpalo su 90 mmol/L moline koncentracija.

Perspėjimai ir atsargumo priemonės
1.KALIBRATORIUS turi būti sandėliuojamas kambario temperatūroje.
2.Kiekviena ampulė turi 0.75 mL tirpalo. Šis tūris atitinkamai sumažina garavimo koncentraciją kelioms valandoms po ampulės perlaužimo. Ampulės skirtos tik vienkartiniam naudojimui.

Naudojimo instrukcijos
1.Švelniai vartykite, kad užtikrintumėte turinio homogeniškumą.
2.Prieš atidarymą, apverskite ampulės kakliuką arba padaužykite ampulės dugną į kietą paviršių, kad pašalintumėte tirpalą iš kakliuko.
3.Padėkite ampulę į ampulės perlaužimo poziciją.
4.Uždėkite apsauginę rankovę ant ampulės kakliuko.
5.Laikydami ampulę viena ranka ir naudodami kitos rankos nykštį ir rodomąjį pirštą nulaužkite kakliuką.
6.Bandinį naudokite tiesiai iš ampulės. Naudokite naują Sweat-Check paėmimo vamzdelį, kad išvengtumėte tirpalo užteršimo.
7.KALIBRATORIAUS tirpalo tyrimui naudokite vartotojo vadove pateikiamas procedūras.

Tikėtinos vertės
Sweat-Check savitojo laidumo elementas turi ypač stabilią atsako charakteristiką, kuri iš esmės yra linijinę per kritinį intervalą nuo 75 iki 110 mmol/L. Pagrindinis kalibravimo tikslas yra užtikrinti, kad elemento temperatūra yra tinkamame intervale, o elektronika veikia įprastai.
Jeigu savitojo laidumo elementas neturi druskos arba vandens likučių, rodmuo su ±2 verte nuo etiketėje pateiktos 90 mmol/L vertės, nurodo labai aukštą patikimumo lygį. Jeigu šis rodmuo nepatenka į nurodytą intervalą, atlikite prietaiso kalibravimą pagal vartotojo vadove pateiktas instrukcijas.

Katalogo numeris SS-140

Wescor, Inc
459 South Main Street, Logan, Utath 84321
JAV
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Faks.: 435 752 4127

IS20A46

Glass encapsulated calibrator solution for sweat-chek™ conductivity analyzer

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product form	:	Mixture
Trade name	:	CALIBRATOR for Sweat-Chek™
Product code	:	SS-140
Product group	:	Trade product

1.2. Relevant identified uses of the substance or mixture and uses advised against

1.2.1. Relevant identified uses

Industrial/Professional use spec	:	For professional use only
Use of the substance/mixture	:	Sodium Chloride Solution, Saline

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

ELITechGroup Inc.
370 West 1700 South
84321 Logan, UT - USA
T +1 (435) 752-6011 - F +1 (435) 752-4127
qara_ebs@elitechgroup.com - www.elitechgroup.com

1.4. Emergency telephone number

Emergency number	:	Contact your distributor or poison control center in your country. InfoTrac Emergency Response: Calls within the USA, phone: 1-800-535-5053. Calls outside the USA, phone: +1 352-323-3500 (call collect) Customer ID: #90104 (NOTE: this number is required when a customer calls into either phone number above).

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Not classified

2.2. Label elements

Labeling according to Regulation (EC) No. 1272/2008 [CLP]

Security closing plug for children	:	No
Tactile warning	:	No

2.3. Other hazards

No additional information available

SECTION 3: Composition/Information on ingredients

3.1. Substance

Not applicable

3.2. Mixture

This mixture does not contain any substances to be mentioned according to the criteria of section 3.2 of REACH annex II

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general : Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

First-aid measures after inhalation : Allow victim to breathe fresh air. Allow the victim to rest.

First-aid measures after skin contact : Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse.

First-aid measures after eye contact : Rinse immediately with plenty of water. Obtain medical attention if pain, blinking or redness persist.

First-aid measures after ingestion : Rinse mouth. Do NOT induce vomiting. Obtain emergency medical attention.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms/injuries : Not expected to present a significant hazard under anticipated conditions of normal use.

4.3. Indication of any immediate medical attention and special treatment needed

No additional information available

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Foam. Dry powder. Carbon dioxide. Water spray. Sand.

Unsuitable extinguishing media : Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

No additional information available

5.3. Advice for firefighters

Firefighting instructions : Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent fire-fighting water from entering environment.

Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Emergency procedures : Evacuate unnecessary personnel.

6.1.2. For emergency responders

Protective equipment : Equip cleanup crew with proper protection.

Emergency procedures : Ventilate area.

6.2. Environmental precautions

No additional information available

6.3. Methods and material for containment and cleaning up

No additional information available

6.4. Reference to other sections

See Heading 8. Exposure controls and personal protection.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work.

7.2. Conditions for safe storage, including any incompatibilities

Incompatible products : Strong bases. Strong acids.

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Exposure controls

Personal protective equipment : Avoid all unnecessary exposure.

Other information : Do not eat, drink or smoke during use.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Color	: Colorless.
Odor	: characteristic.
Odor threshold	: No data available
pH	: No data available
Relative evaporation rate (butyl acetate=1)	: No data available
Melting point	: No data available
Freezing point	: No data available
Boiling point	: 100 °C
Flash point	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: Non flammable
Vapor pressure	: No data available
Relative vapor density at 20 °C	: No data available
Relative density	: No data available
Solubility	: Water: No available data
Log Pow	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidizing properties	: No data available
Explosion limits	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No additional information available

10.2. Chemical stability

Not established.

10.3. Possibility of hazardous reactions

Not established.

10.4. Conditions to avoid

No additional information available

10.5. Incompatible materials

Strong acids. Strong bases.

10.6. Hazardous decomposition products

No additional information available

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Not classified

Skin corrosion/irritation : Not classified
Based on available data, the classification criteria are not met

Serious eye damage/irritation : Not classified
Based on available data, the classification criteria are not met

Respiratory or skin sensitization : Not classified
Based on available data, the classification criteria are not met

Germ cell mutagenicity : Not classified
Based on available data, the classification criteria are not met

Carcinogenicity : Not classified
Based on available data, the classification criteria are not met

Reproductive toxicity : Not classified
Based on available data, the classification criteria are not met

Specific target organ toxicity (single exposure) : Not classified
Based on available data, the classification criteria are not met

Specific target organ toxicity (repeated exposure) : Not classified
Based on available data, the classification criteria are not met

Aspiration hazard : Not classified
Based on available data, the classification criteria are not met

Potential Adverse human health effects and symptoms : Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

12.1. Toxicity

No additional information available

12.2. Persistence and degradability

CALIBRATOR for Sweat-Chek	
Persistence and degradability	Not established.

12.3. Bioaccumulative potential

CALIBRATOR for Sweat-Chek	
Bioaccumulative potential	Not established.

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Other adverse effects

Additional information : Avoid release to the environment

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste disposal recommendations : Dispose in a safe manner in accordance with local/national regulations.

SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

14.1. UN number

Not regulated for transport

14.2. UN proper shipping name

Proper Shipping Name (ADR) : Not applicable
Proper Shipping Name (IMDG) : Not applicable
Proper Shipping Name (IATA) : Not applicable
Proper Shipping Name (ADN) : Not applicable
Proper Shipping Name (RID) : Not applicable

14.3. Transport hazard class(es)

ADR

Transport hazard class(es) (ADR) : Not applicable

IMDG

Transport hazard class(es) (IMDG) : Not applicable

IATA

Transport hazard class(es) (IATA) : Not applicable

ADN

Transport hazard class(es) (ADN) : Not applicable

RID

Transport hazard class(es) (RID) : Not applicable

14.4. Packing group

Packing group (ADR) : Not applicable
Packing group (IMDG) : Not applicable
Packing group (IATA) : Not applicable
Packing group (ADN) : Not applicable
Packing group (RID) : Not applicable

14.5. Environmental hazards

Dangerous for the environment : No
Marine pollutant : No
Other information : No supplementary information available

14.6. Special precautions for user

- Overland transport

No data available

- Transport by sea

No data available

- Air transport

No data available

- Inland waterway transport

No data available

- Rail transport

No data available

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

15.1.1. EU-Regulations

Contains no REACH substances with Annex XVII restrictions

Contains no REACH candidate substance

Contains no REACH Annex XIV substances.

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Other information : None.

SDS EU Custom - EBS

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

Reason for change: Format change to meet GHS compliance.

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product form	:	Mixture
Product name	:	Sweat Controls for Cystic Fibrosis Testing
Product code	:	SS-150
Product group	:	Trade product

1.2. Relevant identified uses of the substance or mixture and uses advised against

1.2.1. Relevant identified uses

Industrial/Professional use spec	:	For professional use only
Use of the substance/mixture	:	Sodium and Chloride in Simulated Human Sweat Matrix. Sweat Control Levels: 1, 2, and 3.

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

ELITechGroup Inc.
370 West 1700 South
84321 Logan, UT - USA
T +1 (435) 752-6011 - F +1 (435) 752-4127
qara_ebs@elitechgroup.com - www.elitechgroup.com

1.4. Emergency telephone number

Emergency number	:	Contact your distributor or poison control center in your country. InfoTrac Emergency Response: Calls within the USA, phone: 1-800-535-5053. Calls outside the USA, phone: +1 352-323-3500 (call collect) Customer ID: #90104 (NOTE: this number is required when a customer calls into either phone number above).

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Hazardous to the aquatic environment - Chronic Hazard Category 3 H412

Full text of classification categories and H statements : see section 16

2.2. Label elements

Labeling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP) :

GHS07

Signal word (CLP)	:	Warning
Hazard statements (CLP)	:	H317 - May cause an allergic skin reaction H412 - Harmful to aquatic life with long lasting effects
Precautionary statements (CLP)	:	P273 - Avoid release to the environment P302+P352 - IF ON SKIN: Wash with plenty of water
EUH phrases	:	EUH208 - Contains METHYLCHLOROISOTHIAZOLINONE(26172-55-4), METHYLISOTHIAZOLINONE(2682-20-4). May produce an allergic reaction
Security closing plug for children	:	No
Tactile warning	:	No

2.3. Other hazards

Adverse physicochemical, human health and environmental effects : To our knowledge, this product does not present any particular risk, provided it is handled in accordance with good occupational hygiene and safety practice.

SECTION 3: Composition/Information on ingredients

3.1. Substance

Not applicable

3.2. Mixture

Name	Product identifier	%	GHS-US classification
5-chloro-2-methyl-2H-isothiazol-3-one	(CAS No) 26172-55-4 (EC Number) 247-500-7	< 0.5	Acute Tox. 3 (Oral), H301 Acute Tox. 3 (Dermal), H311 Skin Corr. 1B, H314 Eye Dam. 1, H318 Skin Sens. 1, H317 STOT SE 3, H335 Aquatic Acute 1, H400
2-methyl-2H-isothiazol-3-one	(CAS No) 2682-20-4 (EC Number) 220-239-6	< 0.5	Acute Tox. 3 (Oral), H301 Acute Tox. 3 (Dermal), H311 Skin Corr. 1B, H314 Eye Dam. 1, H318 Skin Sens. 1, H317 STOT SE 3, H335 Aquatic Acute 1, H400

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures after inhalation : Remove person to fresh air and keep comfortable for breathing.

First-aid measures after skin contact : Wash skin with plenty of water.

First-aid measures after eye contact : Rinse eyes with water as a precaution.

First-aid measures after ingestion : Call a poison center/doctor/physician if you feel unwell.

4.2. Most important symptoms and effects, both acute and delayed

No additional information available

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Water spray. Dry powder. Foam. Carbon dioxide.

5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire : Toxic fumes may be released.

5.3. Advice for firefighters

Protection during firefighting : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Emergency procedures : Ventilate spillage area.

6.1.2. For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Take up liquid spill into absorbent material.

Other information : Dispose of materials or solid residues at an authorized site.

6.4. Reference to other sections

For further information refer to section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Ensure good ventilation of the work station. Wear personal protective equipment.

Hygiene measures : Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in a well-ventilated place. Keep cool.

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Exposure controls

Appropriate engineering controls : Ensure good ventilation of the work station.

Hand protection : Protective gloves

Environmental exposure controls : Avoid release to the environment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Color	: No data available
Odor	: No data available
Odor threshold	: No data available
pH	: No data available
Relative evaporation rate (butyl acetate=1)	: No data available
Melting point	: Not applicable
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: Not applicable
Vapor pressure	: No data available
Relative vapor density at 20 °C	: No data available
Relative density	: No data available
Solubility	: Water: No data available
Log Pow	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidizing properties	: No data available

Explosion limits : No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

None under recommended storage and handling conditions (see section 7).

10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Not classified

5-chloro-2-methyl-2H-isothiazol-3-one (2682-20-4)	
ATE US (oral)	100.000 mg/kg body weight
ATE US (dermal)	300.000 mg/kg body weight

2-methyl-2H-isothiazol-3-one (26172-55-4)	
ATE US (oral)	100.000 mg/kg body weight
ATE US (dermal)	300.000 mg/kg body weight

Skin corrosion/irritation : Not classified

Serious eye damage/irritation : Not classified

Respiratory or skin sensitization : Not classified

Germ cell mutagenicity : Not classified

Carcinogenicity : Not classified

Reproductive toxicity : Not classified

Specific target organ toxicity (single exposure) : Not classified

Specific target organ toxicity (repeated exposure) : Not classified

Aspiration hazard : Not classified

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : The product is not considered harmful to aquatic organisms or to cause long-term adverse effects in the environment.

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

No additional information available

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste treatment methods : Dispose of contents/container in accordance with licensed collector's sorting instructions.

SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

14.1. UN number

Not regulated for transport

14.2. UN proper shipping name

Proper Shipping Name (ADR) : Not applicable
Proper Shipping Name (IMDG) : Not applicable
Proper Shipping Name (IATA) : Not applicable
Proper Shipping Name (ADN) : Not applicable
Proper Shipping Name (RID) : Not applicable

14.3. Transport hazard class(es)

ADR

Transport hazard class(es) (ADR) : Not applicable

IMDG

Transport hazard class(es) (IMDG) : Not applicable

IATA

Transport hazard class(es) (IATA) : Not applicable

ADN

Transport hazard class(es) (ADN) : Not applicable

RID

Transport hazard class(es) (RID) : Not applicable

14.4. Packing group

Packing group (ADR) : Not applicable
Packing group (IMDG) : Not applicable
Packing group (IATA) : Not applicable
Packing group (ADN) : Not applicable
Packing group (RID) : Not applicable

14.5. Environmental hazards

Dangerous for the environment : No
Marine pollutant : No
Other information : No supplementary information available

14.6. Special precautions for user

- Overland transport

No data available

- Transport by sea

No data available

- Air transport

No data available

- Inland waterway transport

No data available

- Rail transport

No data available

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

15.1.1. EU-Regulations

Contains no REACH substances with Annex XVII restrictions

Contains no REACH candidate substance

Contains no REACH Annex XIV substances.

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Full text of H-phrases:

Acute Tox. 3 (Dermal)	Acute toxicity (dermal) Category 3
Acute Tox. 3 (Oral)	Acute toxicity (oral) Category 3
Aquatic Acute 1	Hazardous to the aquatic environment - Acute Hazard Category 1
Eye Dam. 1	Serious eye damage/eye irritation Category 1
Skin Corr. 1B	Skin corrosion/irritation Category 1B
Skin Sens. 1	Skin sensitization Category 1
STOT SE 3	Specific target organ toxicity (single exposure) Category 3
H301	Toxic if swallowed
H311	Toxic in contact with skin
H314	Causes severe skin burns and eye damage
H317	May cause an allergic skin reaction
H318	Causes serious eye damage
H335	May cause respiratory irritation
H400	Very toxic to aquatic life

SDS EU Custom – EBS

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

Reason for change: Format change to meet GHS compliance.

#42.3

Catalog Number SS-150
GLASS ENCAPSULATED SWEAT CONTROLS FOR CYSTIC FIBROSIS TESTING
For In Vitro Diagnostic Use
Lot No:
Expiration Date: 28 February 2009

Analyte / Instrument	**LEVEL 1** (Source lot 19141) Normal	**LEVEL 2** (Source lot 19142) High Normal / Equivocal	**LEVEL 3** (Source lot 19143) Abnormal
Chloride Chloridometer[1]	34 ± 6 mmol/L	68 ± 11 mmol/L	137 ± 21 mmol/L
Conductivity Wescor® Sweat•Chek™ 3100 and 3120	42 ± 5 mmol/L	77 ± 6 mmol/L	142 ± 12 mmol/L
Osmolality Wescor® Model 5520 Vapor Pressure Osmometer	74 ± 12 mmol/kg	139 ± 12 mmol/kg	281 ± 22 mmol/kg

[1] Mean calculated using data from Labconco Digital Chloridometer (Labconco Corp., Kansas City MO 64132).

Intended Use
Wescor Sweat Controls for Cystic Fibrosis Testing are assayed controls intended as a means of validating the measurement of conductivity[A], osmolality, or chloride in patient samples.

Product Description
Wescor Sweat Controls for Cystic Fibrosis Testing are liquid, ready to use, and require no reconstitution or dilution. They are supplied in three levels, representing normal, high normal/equivocal, and abnormal electrolyte concentrations. There are 36 ampules per box, 12 x 0.75 mL of each level. They are prepared in an aqueous simulated human sweat matrix[B] to which preservatives, including 0.05% sodium azide have been added.

Warnings and Precautions
The Wescor Sweat Controls for Cystic Fibrosis Testing do not contain any human source material. No special precautions are required in handling the product other than those routinely used in the laboratory. Dispose of properly. Sodium azide may form metal azides in plumbing and pose a threat of explosion.

Storage and Stability
1. The Sweat Controls should be stored at room temperature.

Each ampule contains 0.75 mL of solution. This volume adequately mitigates evaporative concentration for a few hours after the ampule is broken. Ampules are intended for one-time use only.

Instructions for Use
1. Invert gently to ensure homogeneity of the contents.
2. Before opening, flip the neck of the ampule or tap the bottom of the ampule against a hard surface to clear solution from the neck.
3. Place the ampule in the ampule organizer in the position marked for breaking ampules.
4. Place the safety sleeve over the neck of the ampule.
5. Holding the ampule organizer down against the counter, grasp the neck of the ampule firmly between thumb and forefinger and snap the neck off.
6. Sample directly from the ampule, use a fresh Sweat Chek™ take up tube, micropipettor tip, or other sample loading device each time to avoid contamination of the solution.
7. Treat the controls as you would a patient sample in accordance with the manufacturer's requirements of the test method for each type of analysis: Chloride, Sodium, Conductivity, Osmolality.

Expected Values
The expected values have been established in the laboratory and from interlaboratory data using the listed manufacturer's instruments. Use of control materials having known component concentrations are an integral part of diagnostic procedures. Monitoring of control values establishes intralaboratory parameters for accuracy and precision of the test method. Each laboratory should establish its own quality control standards for the test method used.

Limitations
Any future changes made by the manufacturer of a test method may give a different value from the one indicated. Limitations of the test method are included in the information provided by the instrument manufacturer.

References

[A] Hammond KB, Turcios NL, Gibson LE. Clinical Evalualuation of the Macroduct Sweat Collection System and Conductvity Analyzer in the Diagnosis of Cystic Fibrosis. Pediatrics 1994; 124: 255-260.

[B] Emrich HM, Stoll E, Colombo JP, Richterrich R, Rossi E: Sweat Composition in Relation to Rate of Sweating in Patients with Cystic Fibrosis of the Pancreas, Pediatric Research, 2: 464-478 (1968).

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Gamintojo pavadinimas: ELITechGroup Inc.
(d.b.a. Wescor, Inc.)

Gamintojo adresas: 370 West 1700 South
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Įgaliotas atstovas Europoje: **MT Promedt Consulting, GmbH**
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www.mt-procons.com

Pagal savo atsakomybę skelbia, kad nurodyti produktai:

Produkto pavadinimas:	Sweat-Check™
Modelio numeris:	3120
Įrangos tipas:	Prakaito analizatorius, paremtas laidumu, prijungiamas prie elektros tinklo
GMDN kodas:	60268 (tik prietaisas)
IVDD klasifikacija:	Kita / Bendra ... nepateikiama A ar B, ar savitikros sąraše

atitinka RoHS 2 Direktyvos (2011/65/ES) reikalavimus, taikomą Europos Sąjungos Tarybos direktyvos *invitro* medicinos prietaisų IVDD 98/79/EB dalį ir susijusius esminius I priedo reikalavimus. Taikomi toliau pateikti standartai:

EN 1040:2008	EN 55022:2006+A1:2007
EN 55011:2006+A1:2007	IEC 61000-4-6:2006
EN 61326-1:2006	IEC 61000-4-8:2001
IEC 61000-4-2:2001, 2008	IEC 61000-4-11:2004
IEC 61000-4-3:2008	IEC 61000-3-2:2005
IEC 61000-4-4:2004	IEC 61000-3-3:2005
IEC 60601-1-2:2007	EN 61010-1:1993, 2001
IEC 60601-1:1988, 1991, 1995	

Taip pat, priedai ir tiekiamos dalys, pateiktos šiame dokumente, atitinka taikomą Europos Sąjungos Tarybos direktyvos *invitro* medicinos prietaisų IVDD 98/79/EB dalį ir susijusius esminius I priedo reikalavimus.

Ši deklaracija taikoma pačiam prietaisui ir priedams bei tiekiamoms medžiagoms, pateikiamiems toliau.
Priedai ir tiekiamos medžiagos

AC-071	Ampule Organizer for Sweat Controls
SS-006	Deionized Water, 60 mL bottle, with dropper
SS-044	Take-Up Tubes, 14 inch, package of 100
SS-045	Syringe/Needle Set, 3 ea:1 cc & #22 blunt needle
SS-107	Small sealable containers, 6 each
SS-140	Sweat-Chek Calibrator, 0.75 mL, 90 mmol/L, pk/60
SS-150	Sweat Controls; L1, L2, L3 12ea; 36 0.75 mL ampules

Nurodyti objektai turi CE ir IVD žymėjimus.

Techninė rinkmena saugoma ELITechGroup Inc. Biomedical Systems Division, įsikūrusiame 370 West 1700 South, Logan, Utah, 84321, JAV, o kopija pateikta mūsų įgaliotam atstovui Europoje.

IVD CE

/parašas/	2016 m. gruodžio 22 d.	Logan, Utah, JAV
Dawn T. Perdue	Data	Vieta
Kokybės užtikrinimo direktorius		

Išversta teisingai pagal mano žinias ir įsitikinimus. Tekstas yra išverstas teisingai ir tiksliai bei be pakeitimų prasmėje.
Aš esu užtikrintas, kad lietuvių kalbos vertimas atitinka originalų dokumentą.

Vaidas Vilmantas (MB „Beikeris“, įm .k. 304539005)

#42.1.2; 42.1.3

EC DECLARATION OF CONFORMITY

ELITechGroup
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Manufacturer's Name:	ELITechGroup Inc. (d.b.a. Wescor, Inc.)
Manufacturer's Address:	370 West 1700 South Logan, Utah 84321 USA
European Authorized Representative:	**MT Promedt Consulting, GmbH** Altenhofstr. 80 D-66386 St. Ingbert / Germany Tel.: +49 6894 - 58 10 20 Fax: +49 6894 - 58 10 21 www.mt-procons.com

Declares, under sole responsibility, that the follow product,

Product Name:	Sweat·Chek™
Model Number:	3120
Type of Equipment:	AC line-powered, Conductivity-based Sweat Analyzer
GMDN Code:	60268 (Device Only)
IVDD Classification:	Other/General...not under List A or B or Self-Testing

Conforms to the requirements of RoHS 2 Directive (2011/65/EU), the applicable section of the European Union Council Directive for InVitro Medical Devices, IVDD 98/79/EC, and the associated Essential Requirements under Annex I. The following standards have been applied:

EN 1040: 2008
EN 55011:2006 +A1: 2007

EN 61326-1 2006
IEC 61000-4-2:2001, 2008
IEC 61000-4-3:2008
IEC 61000-4-4:2004
IEC 60601-1-2: 2007
IEC 60601-1: 1988, 1991, 1995

EN 55022: 2006 + A1: 2007
IEC 61000-4-6:2006

IEC 61000-4-8:2001
IEC 61000-4-11:2004
IEC 61000-3-2:2005
IEC 61000-3-3:2005
EN 61010-1: 1993, 2001

Additionally, the Accessories and Supplies listed hereafter conform to the requirements in the applicable section of the European Union Council Directive for InVitro Medical Devices, IVDD 98/79/EC, and the associated Essential Requirements under Annex I.

This declaration applies to the instrument itself and to the accessories and supplies listed hereafter.
Accessories and Supplies

AC-071	Ampule Organizer for Sweat Controls
SS-006	Deionized Water, 60 mL bottle, with dropper
SS-044	Take-Up Tubes, 14 inch, package of 100
SS-045	Syringe/Needle Set, 3 ea: 1 cc & #22 blunt needle
SS-107	Small sealable containers, 6 each
SS-140	Sweat-Chek Calibrator, 0.75 mL, 90 mmol/L, pk/60
SS-150	Sweat Controls; L1, L2, L3 12ea; 36 0.75 mL ampules

And as such bears the CE and IVD markings.

A technical file is maintained at ELITechGroup Inc. Biomedical System Division located at 370 West 1700 South, Logan, Utah, 84321, USA and a copy is provided to our European Authorized Representative.

IVD CE

Dawn T. Perdue — Director of Quality Assurance

22 Dec 2016 — Date

Logan UT U.S.A. — Location

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Manufacturer's Name:	ELITechGroup Inc. (d.b.a. Wescor, Inc.)
Manufacturer's Address:	370 West 1700 South Logan, Utah 84321 USA
European Authorized Representative:	**MT Promedt Consulting, GmbH** Altenhofstr. 80 D-66386 St. Ingbert / Germany Tel.: +49 6894 - 58 10 20 Fax: +49 6894 - 58 10 21 www.mt-procons.com

Declares, under sole responsibility, that the following Class I items that are part of the Macroduct Supply Kit (SS-032),

Item Number:	SS-107	Small Sealable Containers
GMDN code:	16291	
Item Number:	SS-142	Macroduct Collector
GMDN Code:	60298	

Type of Equipment: Supplies used to collect and transport sweat samples for the Cystic Fibrosis (CF) analysis with Model 3700-SYS Macroduct®.

Conforms to the applicable sections of the European Union Council Directive concerning medical devices, MDD 93/42/EEC, and is classified as a Class I medical device and therefore bears the CE Marking as a Class I medical device.

As such, this item bears the CE marking.

CE

Dawn T. Perdue — 19 Jan 2017 — Logan, UT U.S.A.

Dawn T. Perdue
Director of Quality Assurance

Date

Location

EB ATITIKTIES DEKLARACIJA

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Pagal savo atsakomybę skelbia, kad nurodyti I klasės produktai, kurie yra Macroduct Supply Kit (SS-032) dalis:

Produkto numeris:	SS-107	Small Sealable Containers
GMDN kodas:	16291	
Produkto numeris:	SS-142	Macroduct Collector
GMDN kodas:	60298	

Įrangos tipas: tiekiamos medžiagos naudojamos surinkti ir gabenti prakaito mėginius, skirtus cistinės fibrozės (CF) analizei su Model 3700-SYS Macroduct®.

atitinka taikomus Europos Sąjungos Tarybos direktyvos medicinos prietaisų MDD 93/42EEB dalių reikalavimus ir yra klasifikuojami kaip I klasės medicinos prietaisai, todėl jiems naudojamas CE žymėjimas kaip I klasės medicinos prietaisui.

Nurodyti objektai turi CE žymėjimus.

CE

/parašas/	2017 m. sausio 19 d.	Logan, Utah, JAV
Dawn T. Perdue Kokybės užtikrinimo direktorius	Data	Vieta

Išversta teisingai pagal mano žinias ir įsitikinimus. Tekstas yra išverstas teisingai ir tiksliai bei be pakeitimų prasmėje.
Aš esu užtikrintas, kad lietuvių kalbos vertimas atitinka originalų dokumentą.

Vaidas Vilmantas (MB „Beikeris“, įm .k. 304539005)