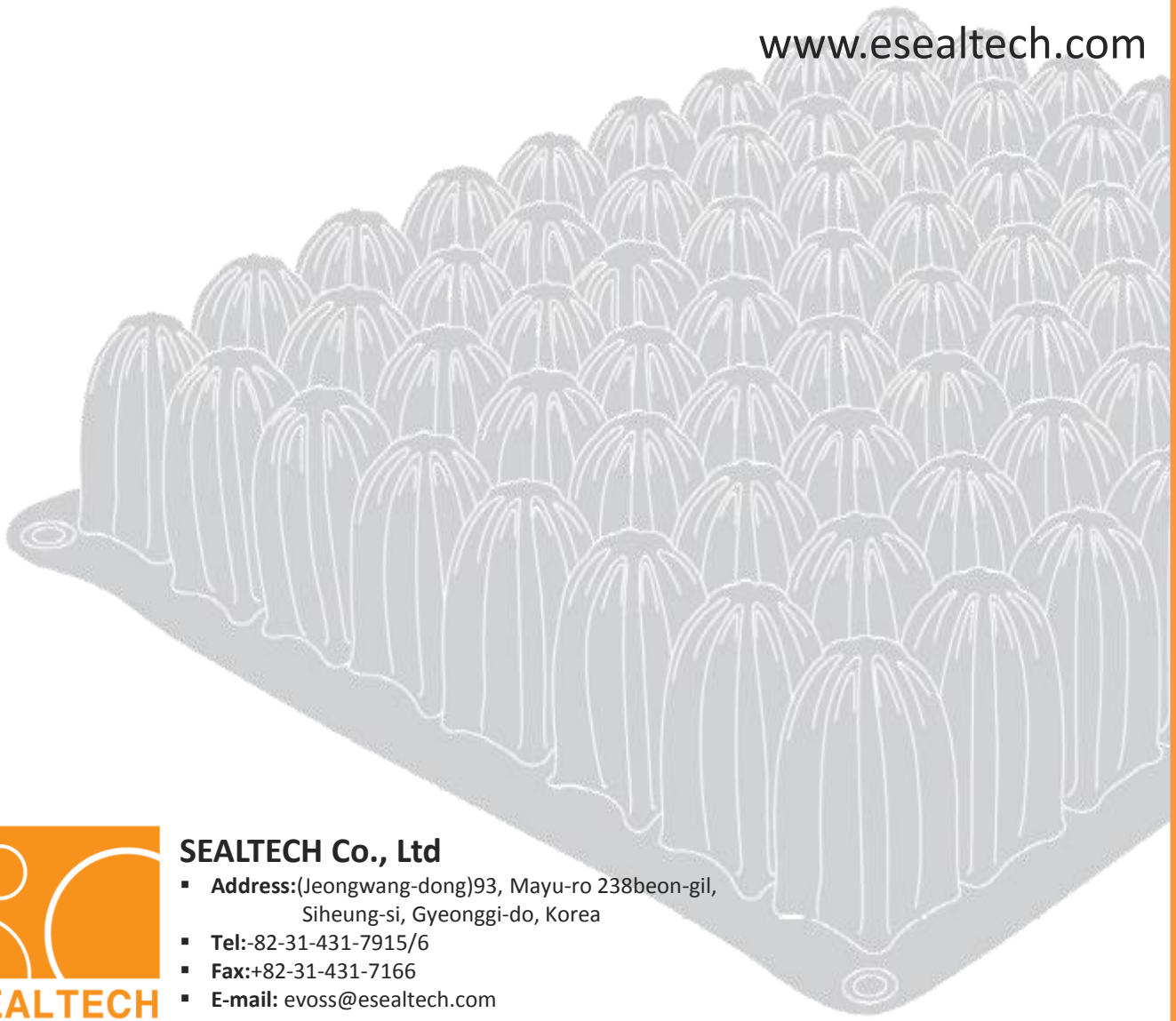
EVOSS Anti-Ulcer Air Cushion

www.esealtech.com



SEALTECH Co., Ltd

- **Address:**(Jeongwang-dong)93, Mayu-ro 238beon-gil, Siheung-si, Gyeonggi-do, Korea
- **Tel:**-82-31-431-7915/6
- **Fax:**+82-31-431-7166
- **E-mail:** evoss@esealtech.com

EVOSS®

Product Information & Feature

Product Information

EVOSS® is composed of a number of discrete air cells in grid combination. EVOSS® is made of a special elastomer with great tensile strength and promises great prevention over Pressure Ulcers.

- **Registration:** Medical Device
- **Product Description**: Air Cushion/Mattress
- **Effectiveness:** Prevent Pressure Ulcer (预防褥疮)
- **Origin:** Republic of Korea
- **HS Code:** 4014.90.9000

Product Feature

EVOSS® guarantees a long–lifetime due to its specialized human skin-friendly materials

Unlike tetragonal shaped cushion, EVOSS® unique octagonal shape implements an untouched experience.

EVOSS® promises anti-biotic effects over sweat or urine by a specialized finishing process.

Thanks to the AI structural engineering system, EVOSS® ensures a comfortable experience over a long time of usage

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EVOSS®

Technical Study Result

Technical Study Result

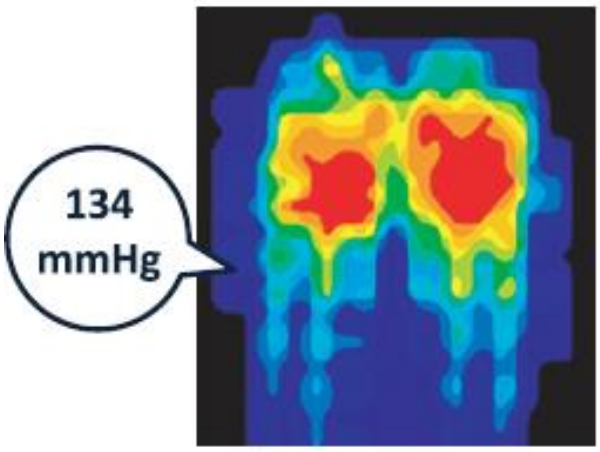
Study Method

- **Model**: Competitor A/Competitor B/Competitor C/EVOSS®
- **Measurement Tool**: Tekscan (USA/ Pressure mapping and force measurement system)
- **Study Institute**: Korea Orthopedics & Rehabilitation Engineering Center

Study Result Overview

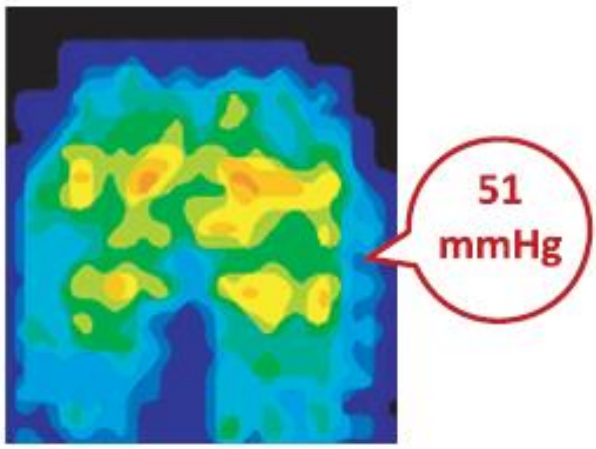
The picture below is showing the pressure level-difference between the EVOSS® user and normal cushion user. The maximum pressure occurring **on a normal cushion is about 134mmHg**, yet it is only **51mmHg on the EVOSS®.** This low-pressure level is even lower than cautious level of skin break in hip area.**(*65-70mmHg)**

Ref. "The pressure level must be maintained below 65-70 mmHg in order to prevent Pressure Ulcers" (National Clinical Thesis & Results)



Sponge type cushion

VS



EVOSS®

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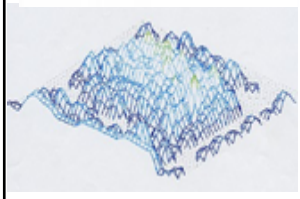
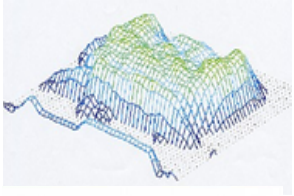
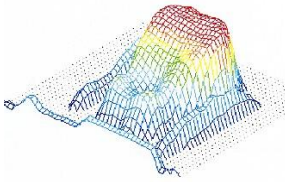
EVOSS®

Comparison Data of Pressure Lv. Over Different Type of Cushions

The pictures below show the maximum value of pressure occurs between skin surface and the product when the cushion is in use.
The lower value implies even distribution of pressure level and it turns out to be a better prevention over Pressure Ulcers.

Product	*Product Type*	*Product Image*	*Pressure Mapping*	*Max. Pressure Lv.*
EVOSS®	**Air Cell Cushion** /Rubber Material			✓ 55 mmHg
Product A	**Air Cell Cushion** /Rubber Material			58 mmHg
Product B	**Gel Type Cushion** /Gel Material			82 mmHg
Product C	**Sponge Cushion** /Sponge Material			132 mmHg

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EVOSS®

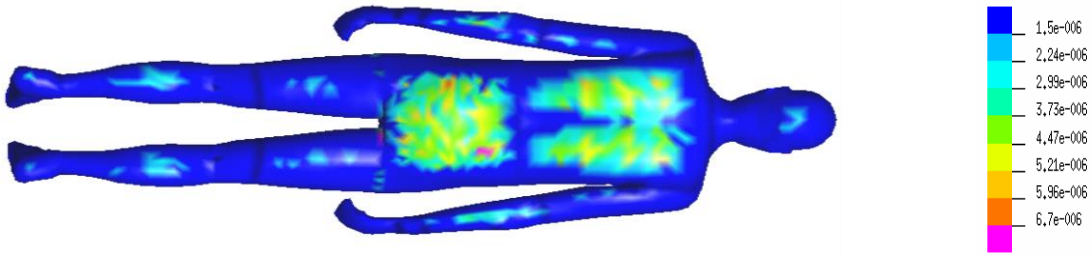
Product Information & Feature

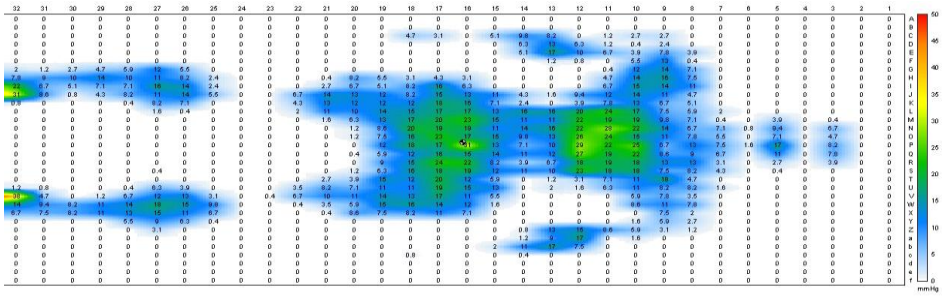
Air Mattress

Using the same material as the EVOSS® cushion, EVOSS® mattress fulfills greater comfort and performance over Pressure Ulcers.

Product Feature

- Ideal for preventing Pressure Ulcers for tetraplegic patients
- Ideal for preventing Pressure Ulcers for patients who are unable to reposition themselves
- Ideal for prevention or even cure of Pressure Ulcers for patients in the process of curing the Ulcers.





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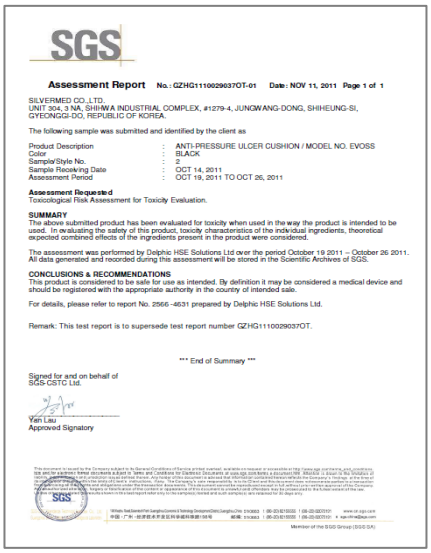
EVOSS®

Awards & Certificates

Certificates



SGS

Assessment Report No.: GZHG1110029037OT-01 Date: NOV 11, 2011 Page 1 of 1

SILVERMED CO.,LTD.
UNIT 304, 3 NA, SHIHWA INDUSTRIAL COMPLEX, #1279-4, JUNGWANG-DONG, SHIHEUNG-SI, GYEONGGI-DO, REPUBLIC OF KOREA.

The following sample was submitted and identified by the client as

Product Description	:	ANTI-PRESSURE ULCER CUSHION / MODEL NO. EVOSS
Color	:	BLACK
Sample/Style No.	:	2
Sample Receiving Date	:	OCT 14, 2011
Assessment Period	:	OCT 19, 2011 TO OCT 26, 2011

Assessment Requested
Toxicological Risk Assessment for Toxicity Evaluation.

SUMMARY
The above submitted product has been evaluated for toxicity when used in the way the product is intended to be used. In evaluating the safety of this product, toxicity characteristics of the individual ingredients, theoretical expected combined effects of the ingredients present in the product were considered.

The assessment was performed by Delphic HSE Solutions Ltd over the period October 19 2011 – October 26 2011. All data generated and recorded during this assessment will be stored in the Scientific Archives of SGS.

CONCLUSIONS & RECOMMENDATIONS
This product is considered to be safe for use as intended. By definition it may be considered a medical device and should be registered with the appropriate authority in the country of intended sale.

For details, please refer to report No. 2566-4631 prepared by Delphic HSE Solutions Ltd.

Remark: This test report is to supersede test report number GZHG1110029037OT.

*** End of Summary ***

Signed for and on behalf of
SGS-CSTC Ltd.

Yan Liu
Approved Signatory

Member of the SGS Group (SGS SA)

SGS

CE

EC Declaration of Conformity

According to Medical Devices Directive 93/42/EEC

Applicant's Name:	SilverMed Co., Ltd.
Applicant's Address:	Unit 304, 3 Na, Shihwa Industrial Complex, #1279-4, Jungwang-dong, Shiheung-si, Gyeonggi-do, Republic of Korea
Manufacturer Name:	SilverMed Co., Ltd.
Manufacturer Address:	Same as Applicant

Declares that the product:

Product Name:	Anti-Pressure Ulcer Cushion
Base Model:	EVOSS
Variant Model:	-

To which this declaration relates is in conformity with the following standard(s) or other normative document(s):

Applicable Regulation:	EN ISO 10993-1 : 2009/AC:2010 EN ISO 10993-10 : 2009/AC:2010 EN ISO 10993-11 : 2010

The test were performed for intracutaneous reactivity and acute systemic toxicity. The test results apply to the particular sample tested and to the specific tests carried out.

This certificate applies specifically to the sample investigated in our test reference number only. The CE markings as shown below can be affixed on the product after preparation of necessary technical documentation.

I, the undersigned, hereby declare that the equipment specified above conforms to the above Standard(s) as described in the attached test report.

Point of contact

Stanley, Kim Tel: 82-2-3667-3986 FAX: 82-2-3667-3987
(Name, telephone and E-mail)

Republic of KOREA, Manager, 18 November, 2011
(Place, date of issue) (Title and signature)

CE

Awards

고령친화우수제품지정서

지정번호 : 제2009-47-C호

품 목 명 : 욕창예방매트리스
제 품 명 : SM-DUB-002
업 체 명 : (주)실테크
대 표 자 : 황 의 석
제품코드 : H12060037001
지정기간 : 2015년 7월 1일~2017년 6월 30일

위 제품을 고령친화산업 진흥법
제12조 및 동법시행령 제9조에 따라
위와 같이 고령친화우수제품으로 지정합니다.

2015년 7월 1일

한국보건산업진흥원장

Senior Friendly Product

No. 2009-320

Korean World-class Product Award 2009

Presented to Sealtech Co, Ltd

In recognition of your company's contributions to the future development of Pressure Alleviation Pad(Air Cell Cushion) and in honor of your dedicated commitment to Korea's high technology exports.

Kyung Hwan Choi
Minister of Knowledge Economy
Republic of Korea

December 14, 2008

The Korean World Class Award

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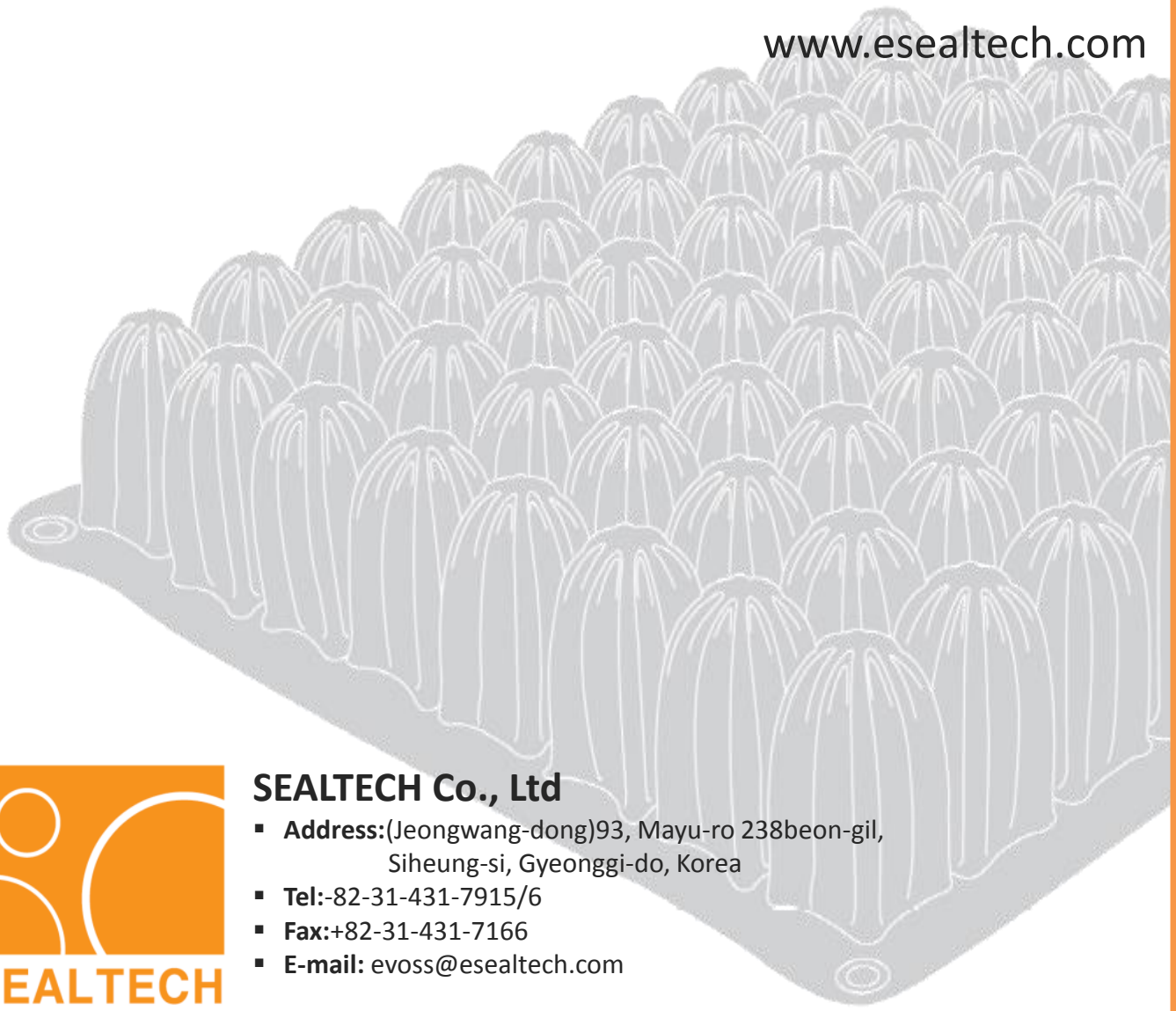

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