

华通威通讯

05 月刊 · 2013 年

NO 17

全球认证 本地化服务 Local Service For Global Certification



- 华通威与苏州大学结成战略合作伙伴 |03
- “2013 年深圳中小出口手机企业质量提升会”顺利召开 |04
- 灯具 GS 认证需满足德国 EK1 决议 |06
- 欧洲 DVB 标准完成第二代颁布 |08



RoHS 2.0

“ 2013 ”

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标准更新

为您带来全球最新的标准信息

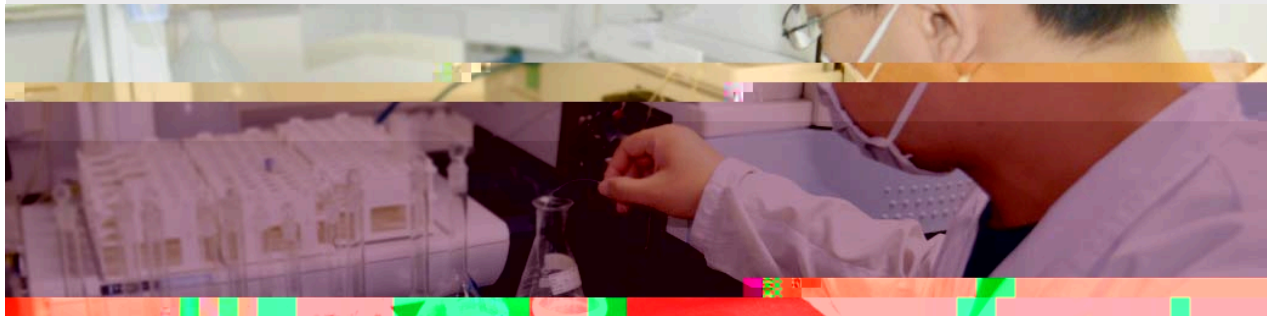


韩国 K-REACH 将实施

2013 4 30 (Draft Act on Registration and Evaluation of Chemicals) K-REACH 2014 5 1 2015 1 1

REACH REACH
K-REACH REACH

(OR)



GS

EK1

: No.518-12

文/华通威 安规检测部



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" QF		DB-T2		"		
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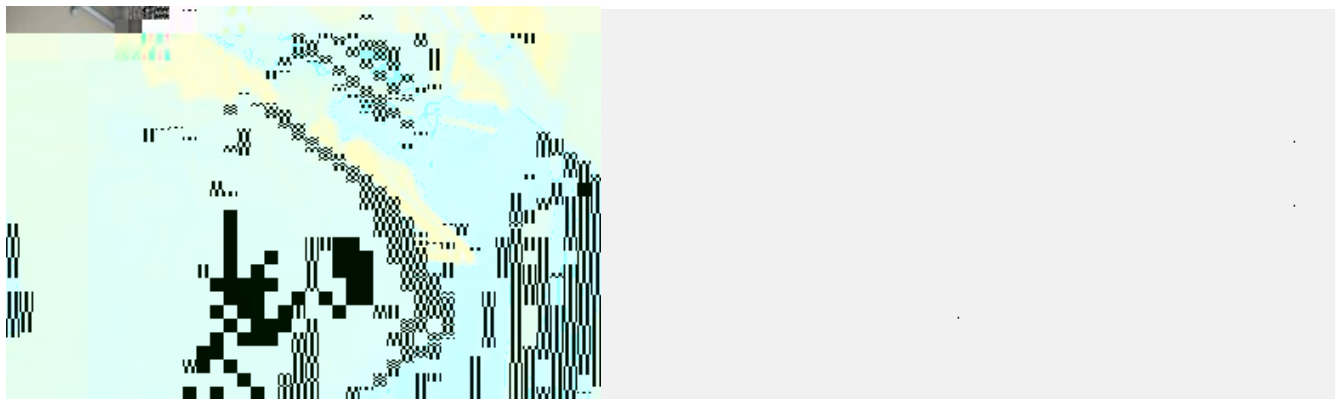
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List RSL)			12 11
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<https://www.vevear.org/assets/1/7/RSL12english-March2013.pdf>



FDA

FDA

[Use of International Standard ISO 10993 - 'Biological Evaluation of](#)

[Medical Devices Part 1: Evaluation and Testing'; Draft Guidance for Industry and Food and Drug Administration Staff;](#)

[Availability](#)

FDA ISO 10993-1

ISO 10993-1

FDA ISO 10993-1

A

B

FDA agrees with the framework established in ISO 10993-1, FDA has made several modifications to the testing identified in that standard for the reasons outlined below

1132

1133

Table 1 – Initial Evaluation Tests for Consideration

Nature of body contact (see 5.2)	Category I		Category II		Category III	
	A	B	A	B	A	B
Contact (see 5.3)						
A – limited (< 24 h)						
B – permanent (> 30 d)						
Intact skin						
Surface area						
Bleached or compromised surface						
Blood contact (direct)						
External contact with tissue/bone/dentin						
Circulation blood						
Tissue/bone						
Implant device						
Blood						

X = ISO Evaluation Tests for Consideration (ISO 10993-1)

O = These additional evaluation tests should be addressed in the submission, either by inclusion of the testing or a rationale for its omission. FDA

Table 2 – Supplementary Evaluation Tests for Consideration

Device type description	ISO 10993-1	Additional tests for consideration
nature of body contact (see 5.2)		
contact duration		
categories		
contact		
limited (< 24 h)		
prolonged (> 24 h to 30 d)		
permanent (> 30 d)		
arc discharge		
active (e.g. electrostimulation)		
biodegradable		
Reproductive		
Intact skin		
Mucosal membrane		
Breached or compromised surface		
Blood path, indirect		
External contact		
Surface device		

X = ISO Evaluation Tests for Consideration (ISO 10993-1)

O = These additional evaluation tests should be addressed in the submission, either by inclusion of the testing or a rationale for its omission. FDA

FDA

MedVatcher Mobile App

MedVatcher is a mobile application (app) that allows individuals to submit voluntary reports of serious medical device problems to the FDA using a smart phone or tablet. The app makes it easier and faster for healthcare professionals, patients and caregivers to send voluntary reports of medical device problems to the FDA compared to the traditional reporting methods - mail, phone or online.

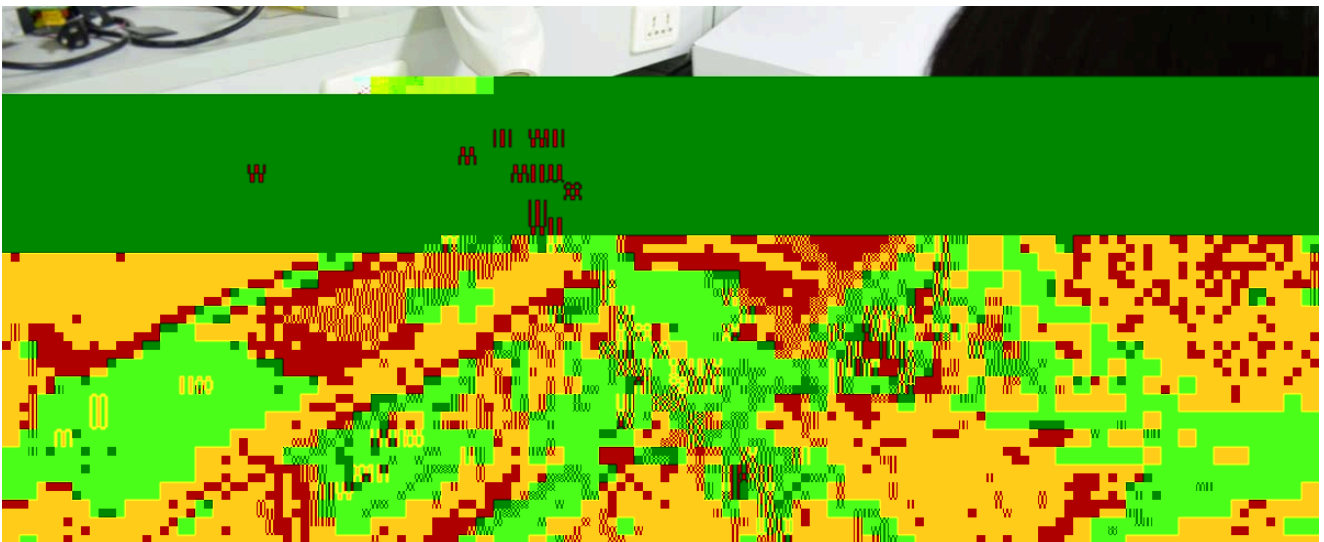
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MedVatcher Mobile App

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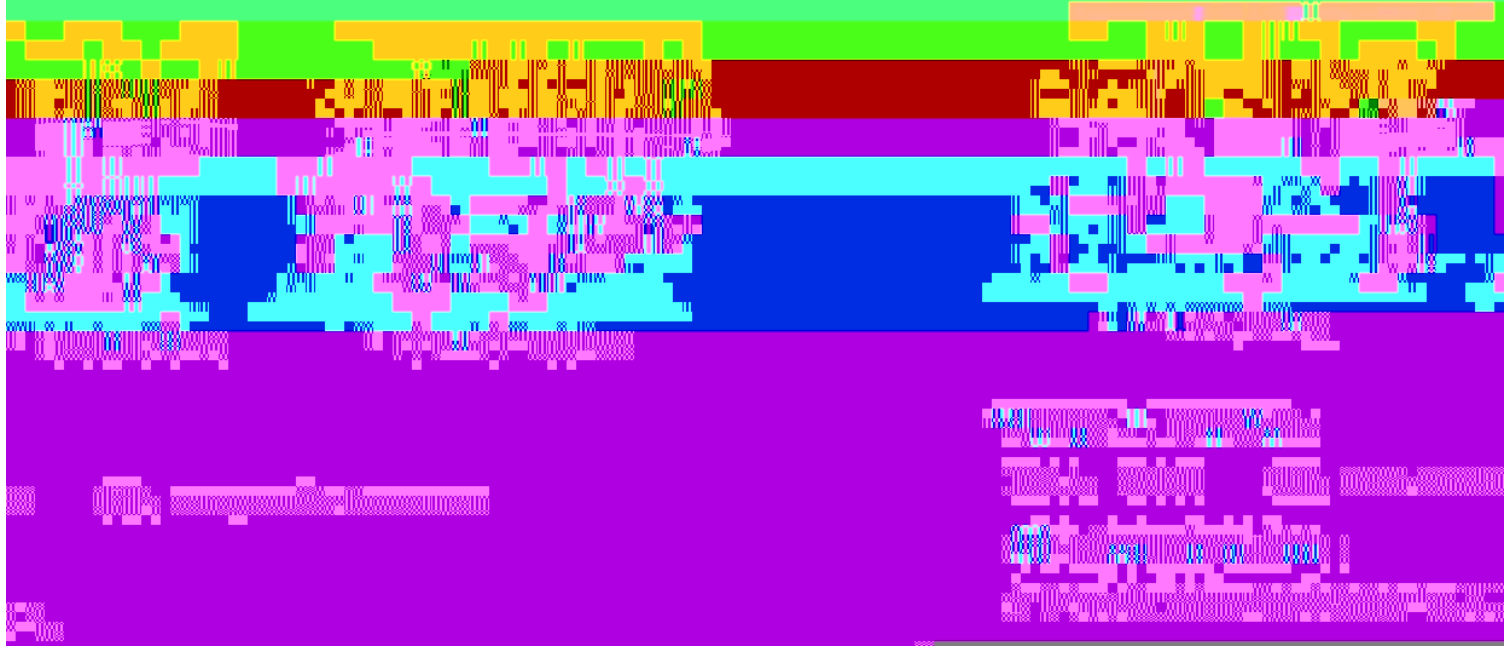
华通威公明EMC实验室

公明实验室投入使用伊始，隆重推出优



流:100A;
:100A.
KV;其它EMS测试项目
将持续致力为客户打造

传导屏蔽室:交流:60A;直流
EMS测试实验室:静电:±2
凭借专业技术和经验,华通威



公明实验室交通指南

自驾车指南

- 1. 从深圳北站乘坐地铁5号线至公明北站下车，步行至公明汽车站乘坐906路公交车至公明实验室下车。
- 2. 从深圳北站乘坐地铁5号线至公明北站下车，步行至公明汽车站乘坐906路公交车至公明实验室下车。
- 3. 从深圳北站乘坐地铁5号线至公明北站下车，步行至公明汽车站乘坐906路公交车至公明实验室下车。

公交线路

906路

906路公交线路图，显示了从深圳北站到公明实验室的路线。路线经过深圳北站、公明北站、公明汽车站、公明实验室等站点。



公明实验室

