

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 ”

5 30

“ 2013 ”

2012



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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ZLS EK1 No.518-12 GS

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EK1 No.518-12

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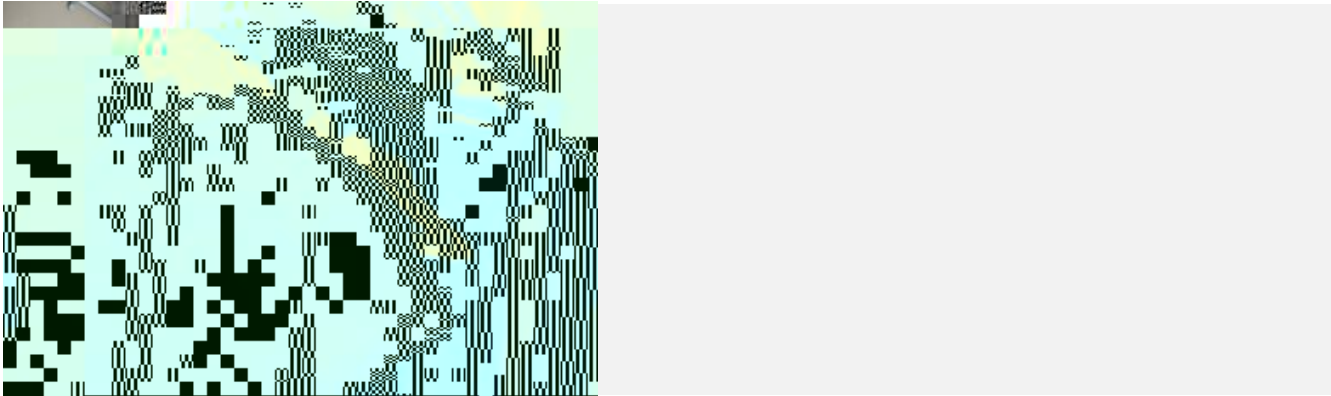
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2013 3 (AAFA) 12 (Restricted Substances
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<https://www.wewear.org/assets/1/7/RSL12english-March2013.pdf>



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Medical Devices Part 1: Evaluation and Testing'; Draft Guidance for Industry and Food and Drug Administration Staff;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
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FDA ISO 10993-1

ISO 10993-1

FDA ISO 10993-1

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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.

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Table 1 – Initial Evaluation Tests for Covid-19 infection

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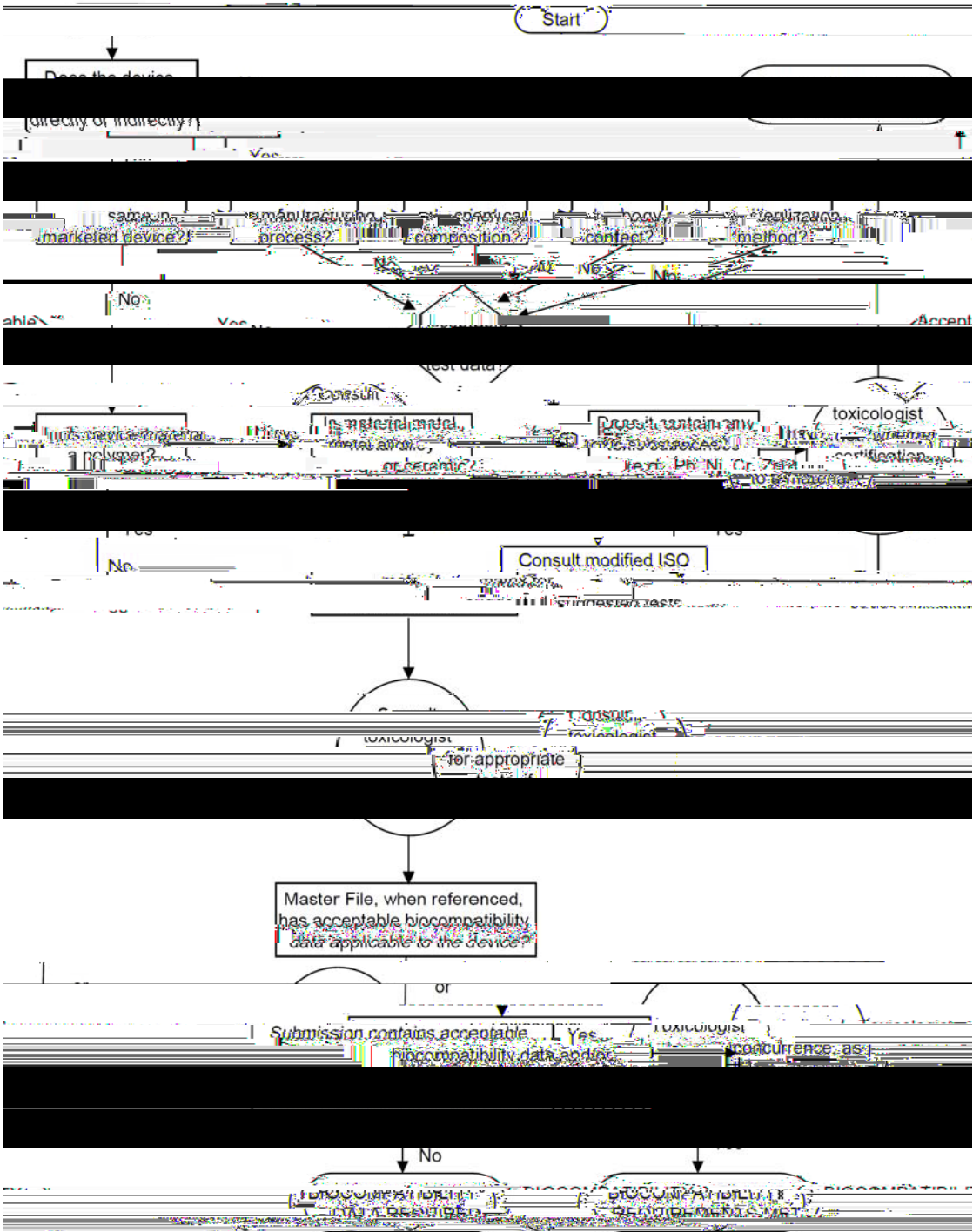
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X = ISO Evaluation Tests for Consideration (ISO 10993-1)

0 = 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	Nature of body contact (see 5.2)	Contact duration	Contact frequency	Contact location	Contact area	Contact force	Contact temperature	Contact environment	Contact duration
Surface device	Mucosal membrane	A	A	A	A	A	A	A	A
Implant device	Tissue/bone	A	A	A	A	A	A	A	A
Implant device	Blood	A	A	A	A	A	A	A	A
Implant device	Tissue/bone	A	A	A	A	A	A	A	A
Implant device	Blood	A	A	A	A	A	A	A	A
Implant device	Tissue/bone	A	A	A	A	A	A	A	A
Implant device	Blood	A	A	A	A	A	A	A	A
Implant device	Tissue/bone	A	A	A	A	A	A	A	A
Implant device	Blood	A	A	A	A	A	A	A	A
Implant device	Tissue/bone	A	A	A	A	A	A	A	A
Implant device	Blood	A	A	A	A	A	A	A	A
Implant device	Tissue/bone	A	A	A	A	A	A	A	A
Implant device	Blood	A	A	A	A	A	A	A	A
Implant device	Tissue/bone	A	A	A	A	A	A	A	A
Implant device	Blood	A	A	A	A	A	A	A	A
Implant device	Tissue/bone	A	A	A	A	A	A	A	A
Implant device	Blood	A	A	A	A	A	A	A	A
Implant device	Tissue/bone	A	A	A	A	A	A	A	A
Implant device	Blood	A	A	A	A	A	A	A	A
Implant device	Tissue/bone	A	A	A	A	A	A	A	A
Implant device	Blood	A	A	A	A	A	A	A	A
Implant device	Tissue/bone	A	A	A	A	A	A	A	A
Implant device	Blood	A	A	A	A	A	A	A	A
Implant device	Tissue/bone	A	A	A	A	A	A	A	A
Implant device	Blood	A	A	A	A	A	A	A	A
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Implant device	Blood	A	A	A	A	A	A	A	A
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Implant device	Blood	A	A	A	A	A	A	A	A
Implant device	Tissue/bone	A	A	A	A	A	A	A	A
Implant									

Attachment C Biocompatibility Flow Chart for the Selection of Toxicity Tests



Attachment C includes a flow chart which outlines how FDA reviewers historically have assessed whether any biocompatibility testing is needed, and how information provided by the sponsor may support the biocompatibility of the final, sterilized device.

[“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”](#)

<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM348890.pdf>

FDA

MedWatcher Mobile App

MedWatcher 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.

MedWatcher

FDA

MedWatcher Mobile App

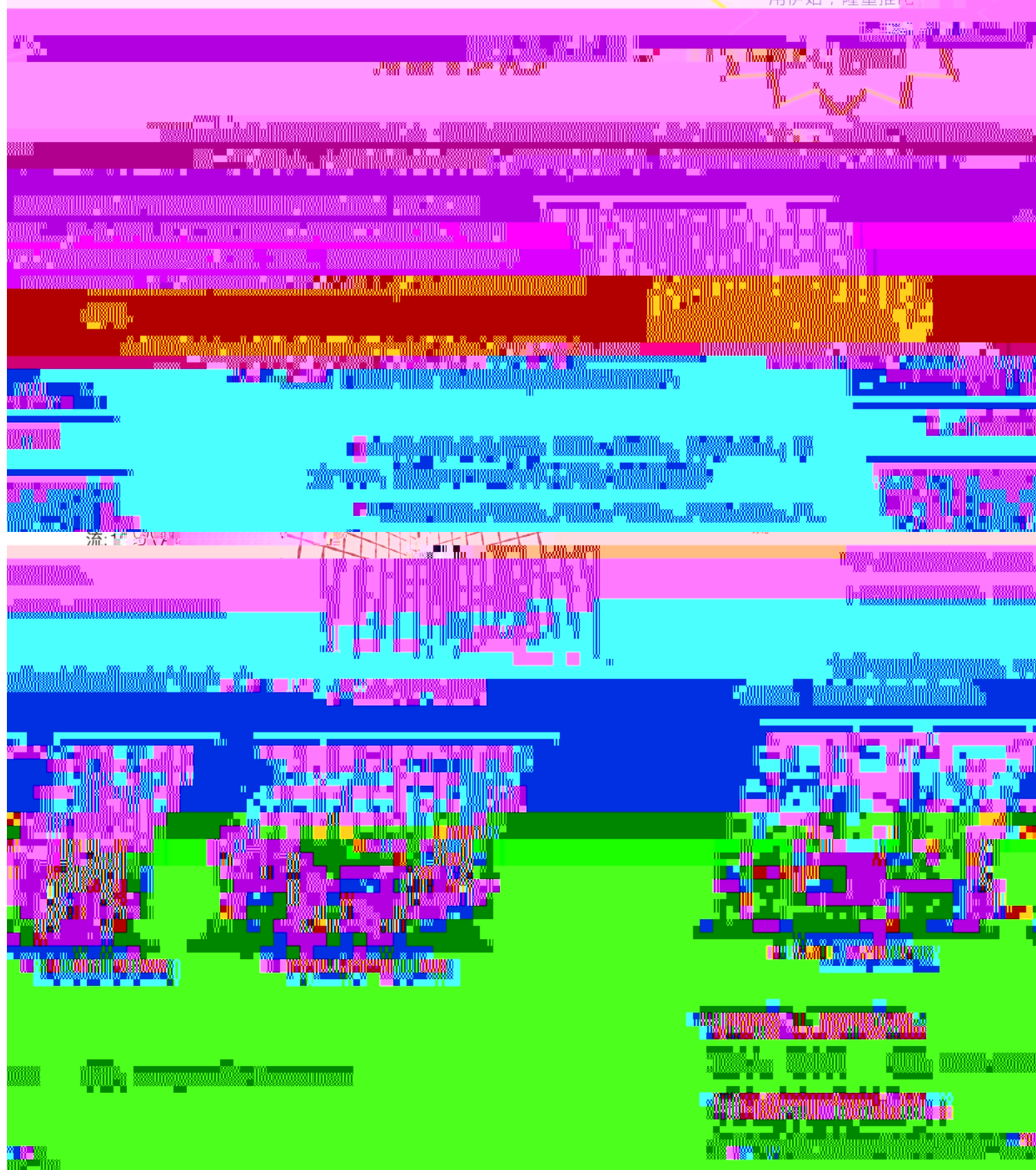
[iTunes Store: MedWatcher App Download²](#)

[Google Play Store: MedWatcher App Download](#)



华通威公明EMC实验室

公明实验室投入使用伊始，隆重推出代



流：1. 学习

公明实验室交通指南

自驾车线路

- ➔ **广州方向路线：**广深高速→虎岗高速→龙大高速→南光高速塘明出口
- ➔ **东莞方向路线：**龙大高速→南光高速塘明出口
- ➔ **深圳方向路线：**南光高速塘明出口

乘坐地铁

- ➔ 乘坐地铁5号线至塘明站，步行约10分钟即可到达。
- ➔ 乘坐地铁6号线至公明北站，步行约10分钟即可到达。



