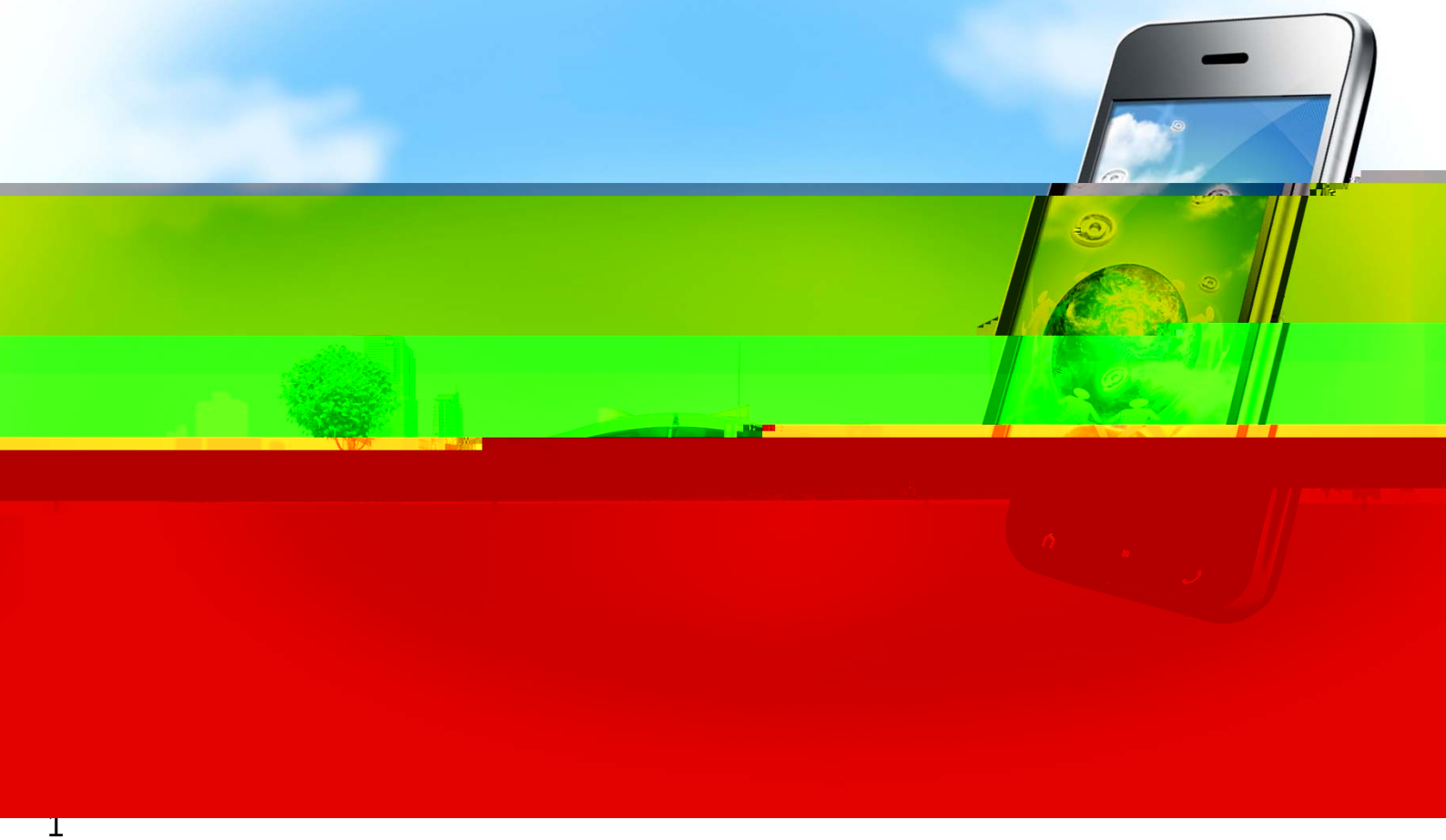
华通威通讯

05 月刊 · 2013 年

NO 17

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



RoHS 2.0

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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

ZLS EK1 No.518-12 GS

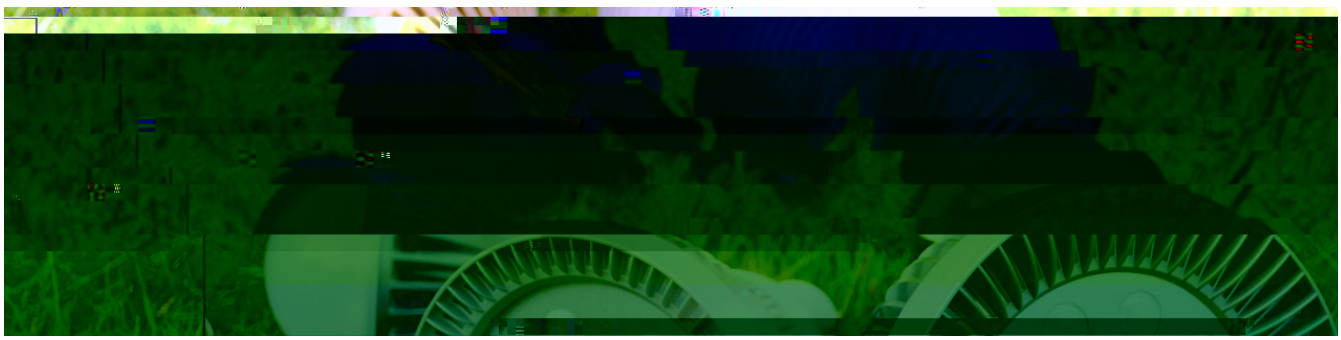
GS TUV VDE

EN60598

EN60598-1 90 60

75 IP1X EN60529

50mm



EK1 No.518-12

EK1

UL

2013 3 26 Jessar Industries Inc.

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DVB

DVB DVB-S2 2006
DVB-T2 2008 6 DVB-C2 2009 1
DVB-T2 8 MHz
TS 50.1 Mbit/s TS
100 Mbit/s T2 “
” QEF DVB-T2 “
5 Mbit/s 1 h 1 ”
10-7 DVB-T2 DVB-T CP-OFDM
QAM DVB-T T2

/

BS DVB-S.2 DTH

DVB-S

AAFA 12

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2013 3 (AAFA) 12 (Restricted Substances List RSL) 12 11 9 18 8 12 , 6 AAFA

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https://www.wewear.org/assets/1/7/RSL12english-March2013.pdf

FDA

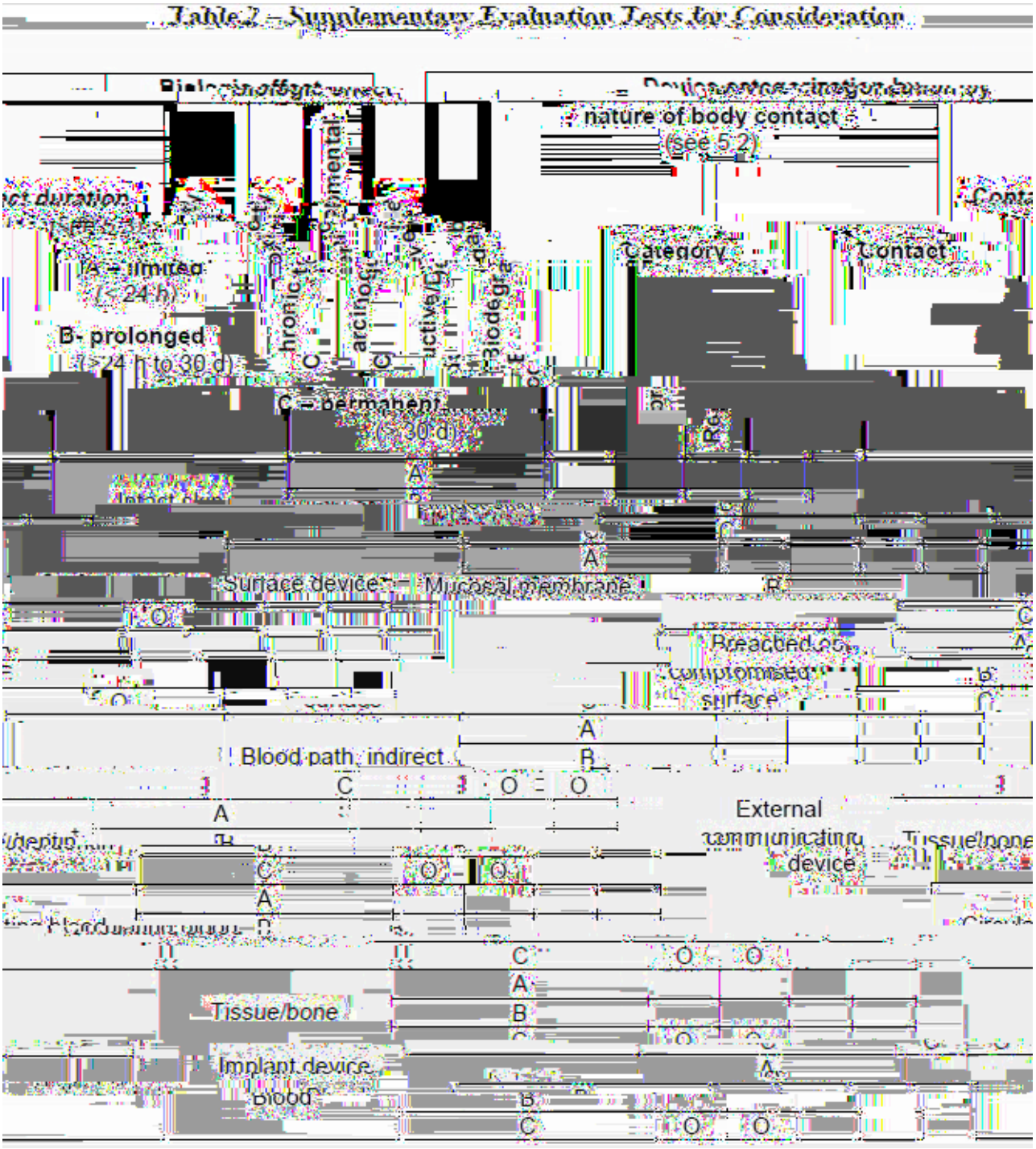
FDA Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing'; Draft Guidance for Industry and Food and Drug Administration Staff; Availability FDA ISO 10993-1 ISO 10993-1

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.

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



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

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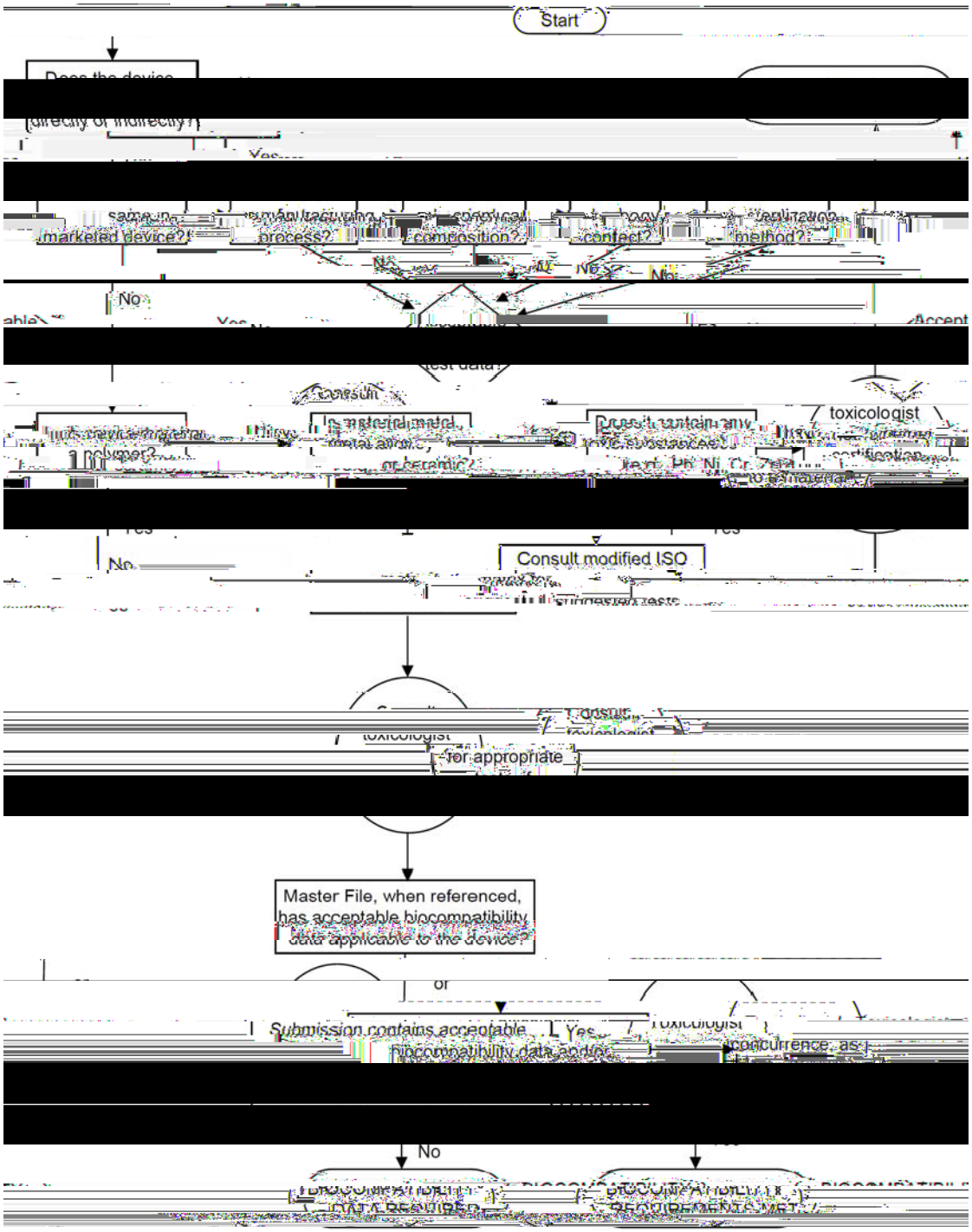
Attachment C Biocompatibility Flow Chart for the Selection of Toxicity Tests



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**

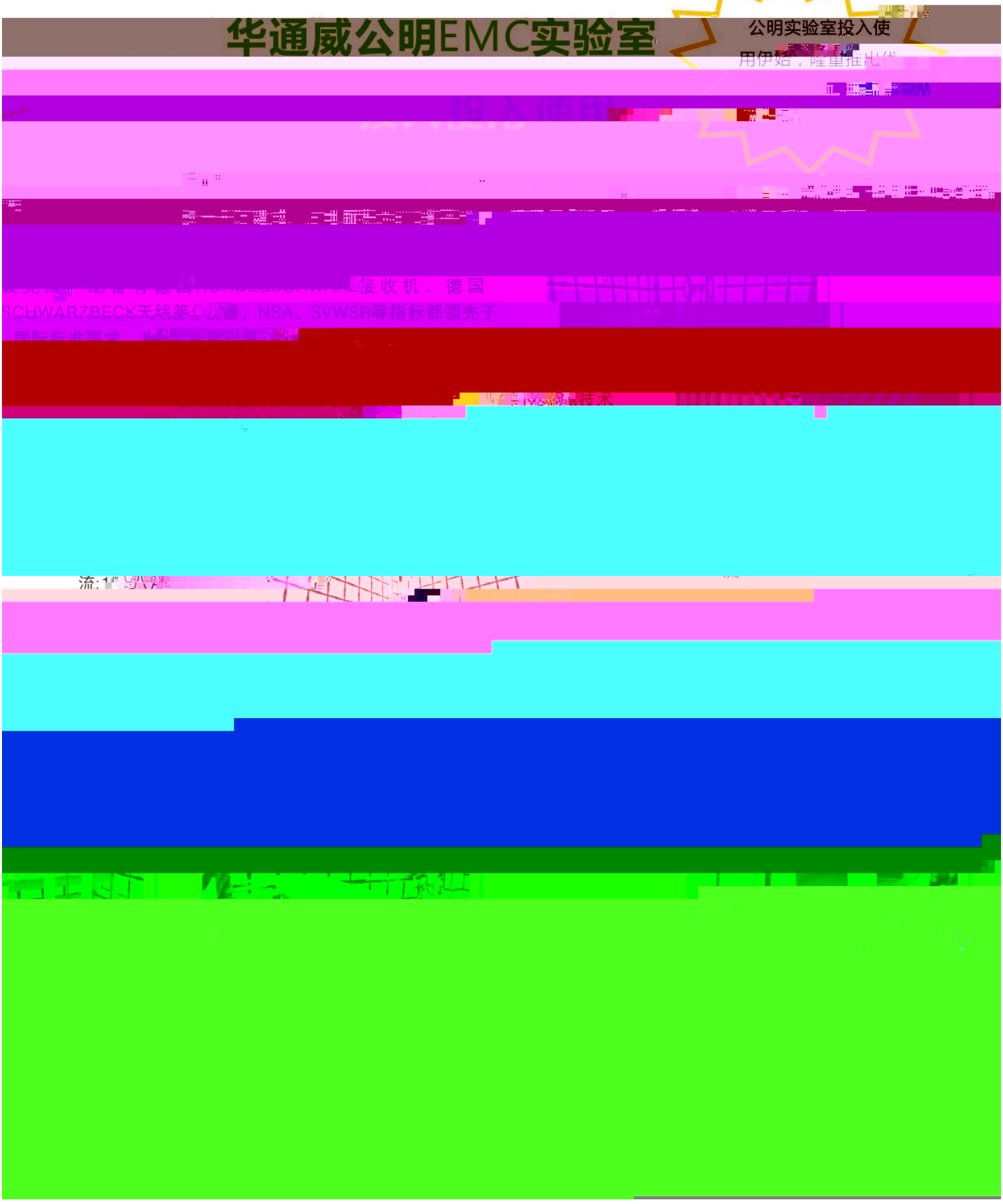
MedWatcher Mobile App

iTunes Store: MedWatcher App Download[2]

Google Play Store: MedWatcher App Download

华通威公明EMC实验室

公明实验室投入使



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