RIGGTEK

自 动 溶 出 系 统

www.riggtek.com

RIGGTEK

目 录

方 便 • 可 靠 • 高 效

DISSOPREP X8 / X15

溶媒制备工作站

DISSOPREP X8 / X15是一套原创的、结构紧凑、方便易用的溶媒制备系统。该系统集过滤、混合、加热、脱气、分配于一体，完全符合USP、EP、ChP、FDA、GLP/GMP对溶出试验中溶质配制的规范要求。

DISSOPREP X8 / X15 溶媒制备工作站

监管：

溶媒制备过程的准确性和可重复性显著影响着溶出试验结果的重现性。

1 溶媒混合的准确性和可重复性

2 溶媒准确移取至溶出杯

3 溶媒的高效加热

4 溶媒的脱气

5 溶媒制备过程的文档化

功能

- 过滤---易于更换滤芯，自动检查过滤能力，定期提示用户更换耗材，原则上滤过的溶媒可防止细菌生长。
- 混合---为浓盐酸、缓冲盐和表面活性剂提供第二入口以提高准确性；混合精度很高，偏差＜0.2%；加装搅拌器以确保溶媒浓度的均匀。
- 加热---在脱气前预热溶媒，提高脱气效率；并能大大节约溶媒在溶出仪中的加热时间。
- 脱气---加热、混合与脱气的组合极大提高了溶媒脱气效率（最终水中含氧量仅3-5ppm）
- 分配---自由设置分配体积，分配时间短，分配体积精度控制在1%以下。
- 记录---实现溶媒制备过程的全程记录和打印，方便审计和溯源。

溶媒制备过程的准确度和可重复性显著影响着溶出试验结果的重现性！

混合、加热和移取

USP：溶媒满足体积精度达到1%，温度平衡至37℃±0.5℃的要求。

结论：

1 标准体积（多组分溶媒的混合中）：必须在标准环境条件下低温注入然后加热；

2 依据USP，如转移900mL溶出溶媒，其重量为897.4g；

3 注意：在加热过程中只有液体的质量是不变的，而密度和体积都在改变；所以在20℃条件下用容量瓶或其他容器测量热的溶媒是错误的，在37℃条件下用比重（密度）来测量溶媒的体积或质量也是错误的。

脱气

USP认识到，在溶媒中溶解的气体可能会影响溶出试验的结果…

建议在进行溶出试验之前通过过滤、加热和搅拌等方法除去溶媒中的气体。

FDA比以前更加关注脱气这一过程，它推荐的方法也是USP所推荐的“过滤、加热、搅拌、真空等方法”。搅拌是通过向溶媒中输送气泡然后通过“滚雪球效应”来实现脱气的目的。

结论：

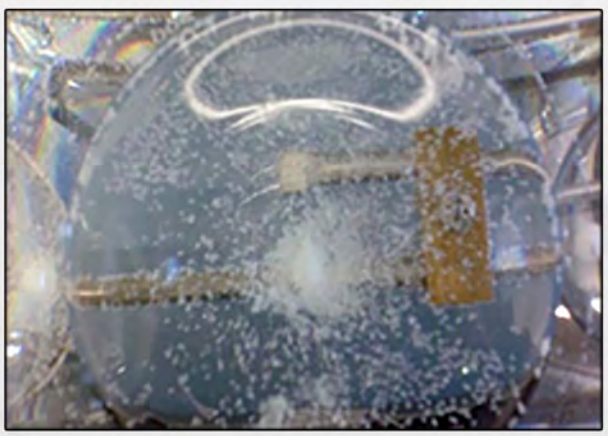
1 脱气是必要的，至少可以避免过饱和；

2 可通过改变溶媒的温度或真空度来实现脱气；

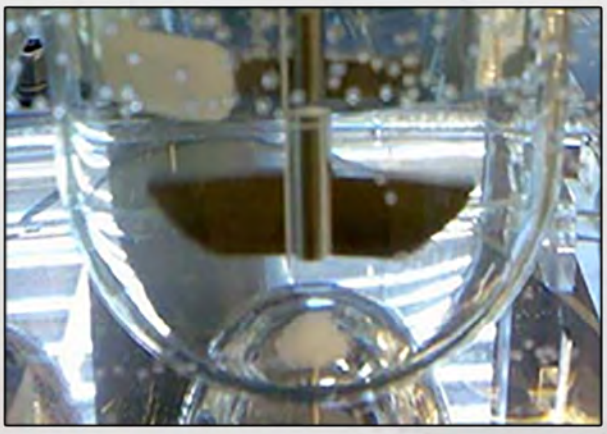
3 不同脱气方法脱气效果的比较必须在溶媒转移到溶出杯中时或者溶出试验正式开始时进行。

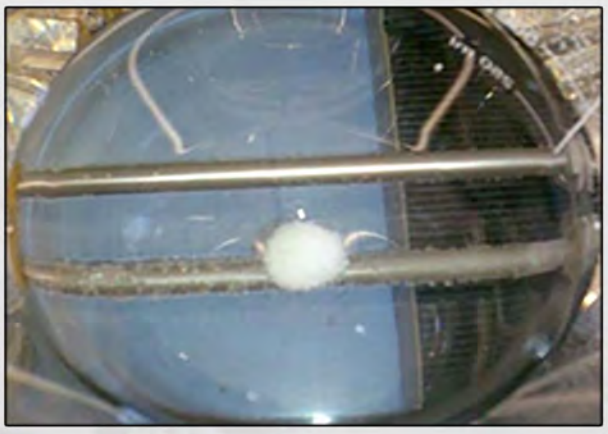
脱气前后效果对比

- 脱气前：



- 脱气后：





DISSOPREP X8 / X15溶媒制备工作站脱气效果

Degassing Efficiency Investigation with DissoPrep X8

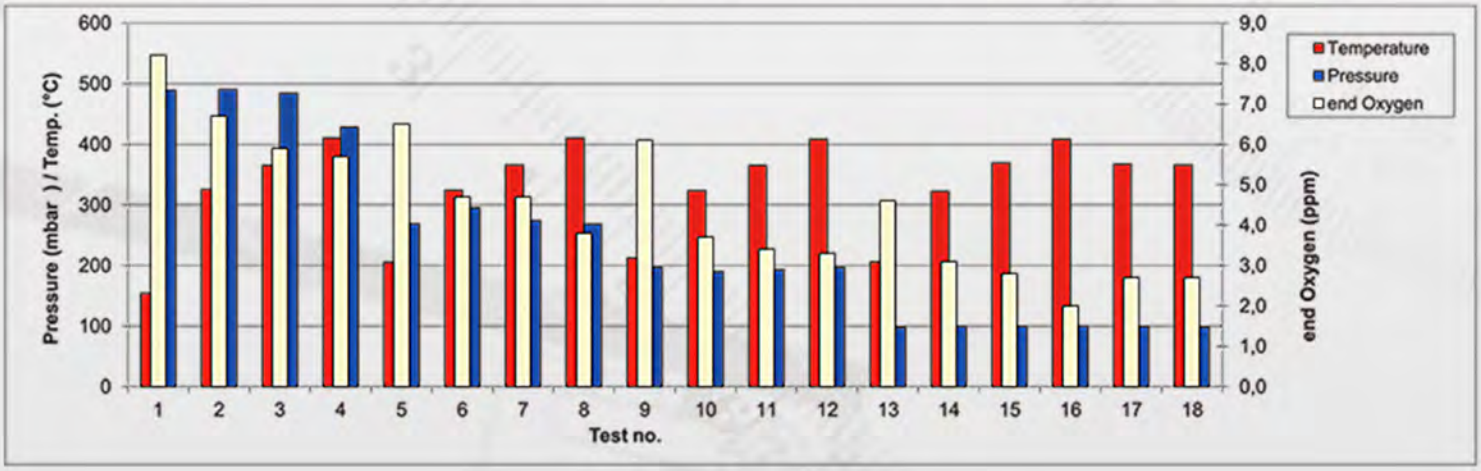
www.riggtek.com
Dipl.- Ing. Hansjuergen Riggenmann

Oxymeter from WTW OXI 330
DissoPrep X8 with Firmware 8.01

★ As long as the vacuum is <300mbar and the temperature is >32℃, a sufficient degassing of typical <5ppm will be reached

★★ The DissoPrep-Routine-Applications(vacuum <100mbar, temperature between 32℃ and 37℃, seconds) are resulting in a fast and very good degassing result!

Method Parameter	Test No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
Temperature set.	°C	20	32	37	42	20	32	37	42	20	32	37	42	20	32	37	42	37	37
Temperature eff.	°C/10	154	325	365	410	205	324	366	410	212	323	365	408	206	322	369	408	367	366
min. Pressure (vacuum)	mbar	489	490	484	428	269	295	274	268	197	190	193	197	98	99	99	100	99	98
Volume	mL	1x 5400	1x 5400	1x 5400	1x 5400	1x 5400	1x 5400	1x 5400	1x 5400	1x 5400	1x 5400	1x 5400	1x 5400	1x 5400	1x 5400	1x 5400	1x 5400	1x 5400	1x 5400
add. Degas Time	sec	120	120	120	120	120	120	120	120	120	120	120	120	120	120	120	120	240	480
start Oxygen	ppm O_2	9,1	8,3	8,1	9,2	8,4	8,4	8,9	8,9	8,6	8,1	8,5	8,2	8,6	8,2	8,4	8,4	8,6	8,5
end Oxygen	ppm O_2	8,2	6,7	5,9	5,7	6,5	4,7	4,7	3,8	6,1	3,7	3,4	3,3	4,6	3,1	2,8	2,0	2,7	2,7
DPX8 routine application															YES	YES			



★ 随着真空度下降到300mbar之下、温度升高到32℃之上，将会得到一个有效的脱气结果（溶氧量＜5ppm）

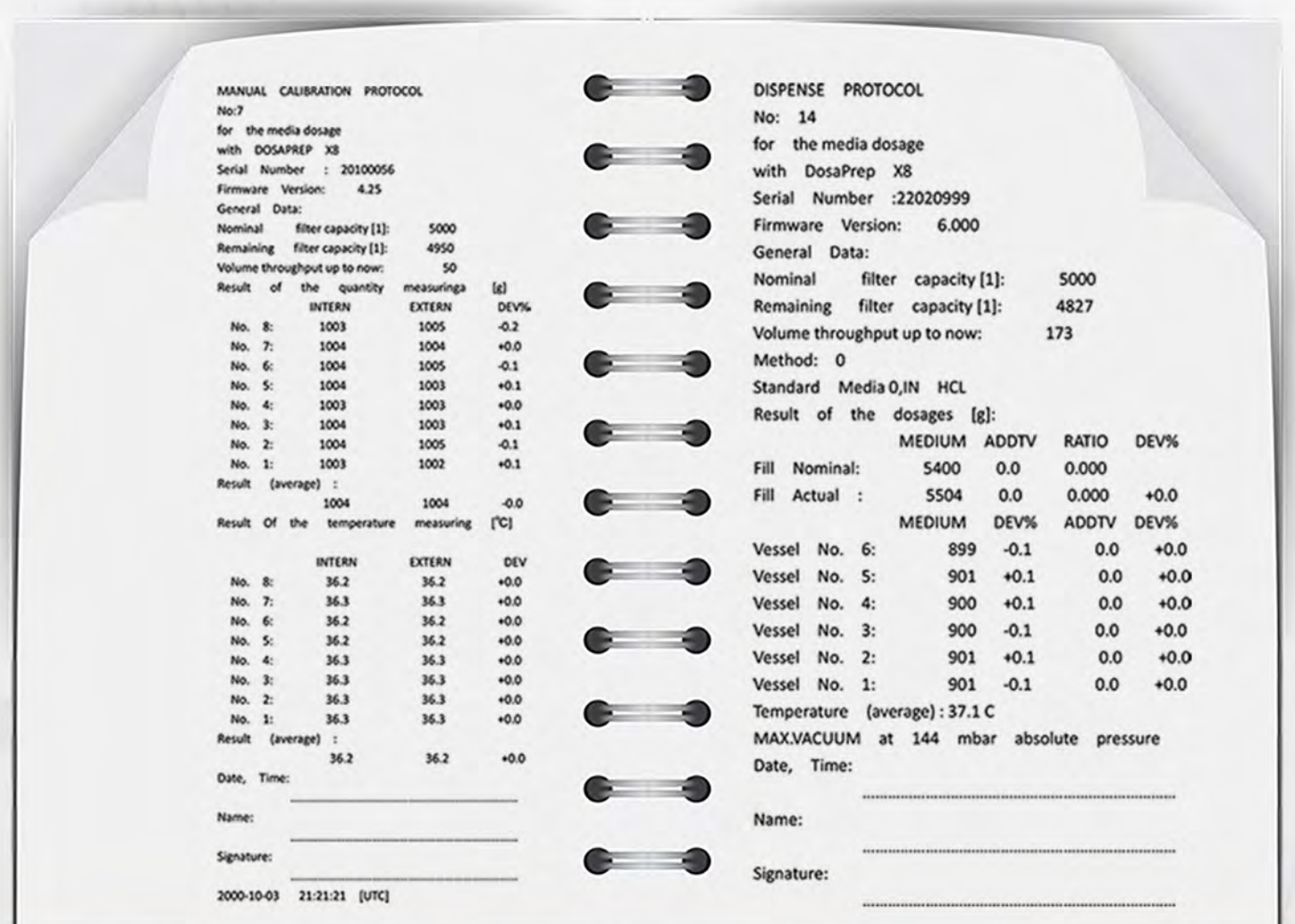
★★ 在该仪器的常规配置（真空度＜100mbar，温度在32℃~37℃之间，脱气时间120秒）即能得到快速而高效的脱气效果

文档化

GLP/GMP：要求建立一个符合规定的溶媒制备的SOP...所有工作步骤必须实现文档化（便于审计）

- 高效：节约时间和金钱成本
- 重复性好：溶媒制备自动化的结果
- 规范：符合USP，EP，ChP，FDA，GLP/GMP的规范要求
- 安全：极大降低了对实验人员的伤害
- 操作便捷、节约空间
- 一键自动校正功能
- 行政文件的简化

DISSOPREP X8 / X15溶媒制备工作站的数据记录提供的文件记录示例



MANUAL CALIBRATION PROTOCOL
No:7
for the media dosage
with DOSAPREP X8
Serial Number : 20100056
Firmware Version: 4.25
General Data:
Nominal filter capacity [1]: 5000
Remaining filter capacity [1]: 4950
Volume throughput up to now: 50
Result of the quantity measuringa [g]

	INTERN	EXTERN	DEV%
No. 8:	1003	1005	-0.2
No. 7:	1004	1004	+0.0
No. 6:	1004	1005	-0.1
No. 5:	1004	1003	+0.1
No. 4:	1003	1003	+0.0
No. 3:	1004	1003	+0.1
No. 2:	1004	1005	-0.1
No. 1:	1003	1002	+0.1
Result (average) :	1004	1004	-0.0

Result Of the temperature measuring [°C]

	INTERN	EXTERN	DEV
No. 8:	36.2	36.2	+0.0
No. 7:	36.3	36.3	+0.0
No. 6:	36.2	36.2	+0.0
No. 5:	36.2	36.2	+0.0
No. 4:	36.3	36.3	+0.0
No. 3:	36.3	36.3	+0.0
No. 2:	36.3	36.3	+0.0
No. 1:	36.3	36.3	+0.0
Result (average) :	36.2	36.2	+0.0

Date, Time: _____
Name: _____
Signature: _____
2000-10-03 21:21:21 [UTC]

DISPENSE PROTOCOL
No: 14
for the media dosage
with DosaPrep X8
Serial Number :22020999
Firmware Version: 6.000
General Data:
Nominal filter capacity [1]: 5000
Remaining filter capacity [1]: 4827
Volume throughput up to now: 173
Method: 0
Standard Media 0,IN HCL
Result of the dosages [g]:

	MEDIUM	ADDTV	RATIO	DEV%
Fill Nominal:	5400	0.0	0.000	
Fill Actual :	5504	0.0	0.000	+0.0

	MEDIUM	DEV%	ADDTV	DEV%
Vessel No. 6:	899	-0.1	0.0	+0.0
Vessel No. 5:	901	+0.1	0.0	+0.0
Vessel No. 4:	900	+0.1	0.0	+0.0
Vessel No. 3:	900	-0.1	0.0	+0.0
Vessel No. 2:	901	+0.1	0.0	+0.0
Vessel No. 1:	901	-0.1	0.0	+0.0

Temperature (average) : 37.1 C
MAX.VACUUM at 144 mbar absolute pressure
Date, Time:
.....
Name:
.....
Signature:
.....

EASYDISS TX6/TX8™溶出仪

EASYDISS TX6/TX8™溶出仪是溶出仪产品领域的可靠主力。采用数控生产技术和现代微处理器设计，确保了最高标准的质量和性能，符合美国药典USP和欧洲药典EP的规范。高效和紧凑的设计，减小了对操作平台的要求，使其成为药物研发和药物质控的理想工具。

EASYDISS TX6/TX8™溶出仪

性能和特点

- 符合EP、USP和ChP现行规范
- 结构稳固、紧凑，使用方便，设计简洁
- 采用通用的配件，不同方法（转篮法、桨法等）之间的切换时间缩短到秒
- 独立的控制器允许每根转轴的单独升高或降低
- 溶出杯支撑板采用316不锈钢材质，表面有特氟龙涂层
- “易中心”溶出杯定位系统，确保溶出杯完美居中
- 内置配液阀的整块PETG材质水浴装置，无泄漏，方便排液和清洗
- 独立的数字加热器和循环系统，超温切断
- 运行完成后打印完整的测试报告，便于审计和溯源
- 菜单引导的校准程序（可打印）

丰富配件

- 激光编码和认证的转轴、搅拌桨、转篮和溶出杯
- 表面有特氟龙涂层的搅拌桨和转篮，可避免腐蚀
- 不同材质的溶出杯及杯盖，如透明玻璃和琥珀色溶出杯、EMC超精密溶出杯、低蒸发杯盖等
- 适用于透皮贴剂的转筒
- 应用于桨碟法的不锈钢网碟
- 自动片剂投药装置，保证各溶出杯投药时间一致
- 适合自动或手动采样的采样针
- 小杯法转换器
- 其他配件和工具

EASYDISS COOL

低温溶出仪

可提供低至4℃的实验条件，已应用于纳米配方药物的研发

可灵活应用于各种温度下的实验条件

SAMPILIO X8

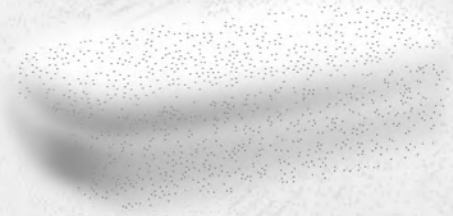
自动取样器

SAMPILIO X8是一款新型的溶出自动取样系统，它采用小体积隔膜泵进行样品收集，结果准确可靠，而且大大提高了工作效率。

SAMPILIO X8自动取样器

用户在使用自动取样器过程中可能会遇到的问题

- 泵不可靠
- 自动取样结果与手动取样结果不一致
- 样品之间的交叉污染
- 采样间隔不够短，不能满足用户的取样次数的要求
- 自动取样器不能满足各种不同的溶出杯连接要求
- 自动取样器操作复杂
- 仪器的清洗和维护很耗时



优势

- 小体积隔膜泵的可靠性
- 与人工操作相当的实验结果
- 降低交叉污染
- 操作间隔时间缩短至2分钟
- 易于操作和处理，便于清洗和维护
- 方便接入各种溶出杯，且可与其他厂家的溶出仪灵活连接

CQS源于德国，是德国RIGGTEK溶出仪在亚太地区的渠道商和合作伙伴。CQS正式入驻中国，为中国用户带来更专业的服务。同时，了解到广大溶出仪用户的需求，CQS与各品牌的耗材供应商合作，为大家带来货期更短，价格更优，品质不变的耗材！希望全方位为溶出仪用户提供各种服务！

RIGGTEK

QZV
Verein zur Qualitätssicherung und Zertifizierung
für den Mittelstand e.V.

QZV DIN EN ISO 9001:2015

CERTIFICATE

The Verein zur Qualitätssicherung und Zertifizierung für den Mittelstand e.V.
certifies that the company

RIGGTEK GmbH
Dissolution Test Systems
Edelsbergstraße 8 – 10
80686 München

has established and maintains a Quality Management System according to DIN EN ISO 9001:2015.
Proved in an audit.

Audit-no.: **12236996**

Conducted by: _____
Prof. Dr. G. Knauer, Professor an der Hochschule München

This certificate was issued the: 20.01.2016 and is valid until: 19.01.2019
Certificate registration no.: **12136996**

For the QZV _____
Prof. Dr.-Ing. Deublein, Professor an der Hochschule München

QZV e.V. Schlierseestr. 46, 81539 München
Registrierungsnummer 33150102 (AICB e.V.)

AICB

RIGGTEK Dissolution Test Systems

EC - DECLARATION OF CONFORMITY

CERTIFICATE NO. CE-EDS-20131119

We RIGGTEK GmbH, at address below, declare under our sole responsibility that the product detailed below to which this declaration relates complies with protection requirements of the following harmonized EC Directives:

- Machinery Directive 2006/42/EC
- Electromagnetic Compatibility Directive 2004/108/EC CE
- Low Voltage Directive 2006/95/EC

This equipment has been designed and manufactured to the following transposed harmonized European Standards:

- BS EN 61010-1:2001 Safety requirements for electrical equipment for measurement, control and laboratory use.- Part 1: General requirements
- BS EN 61326:1998 Electrical equipment for measurement, control and laboratory use - EMC requirements

Responsible Company:	RIGGTEK GmbH, Dissolution Test Systems Edelsbergstrasse 8-10 80686 München Germany
Product Type & Model:	EDS – easyDISS TX6 and TX8
Product Classification:	Light Industrial
Product Functionality:	Dissolution Tester

A technical file for this equipment is retained at the above address.
This Declaration of Conformity was prepared according to EN ISO/IEC 17050-1:2004.

Signature of responsible person

Name of responsible person	Andreas Singer
Position of responsible person	Director
Place and Date of Issue	Munich, 19.11.2013

RIGGTEK Dissolution Test Systems

EC - DECLARATION OF CONFORMITY

CERTIFICATE NO. CE-SX8-20131119

We RIGGTEK GmbH, at address below, declare under our sole responsibility that the product detailed below to which this declaration relates complies with protection requirements of the following harmonized EC Directives:

- Machinery Directive 2006/42/EC
- Electromagnetic Compatibility Directive 2004/108/EC CE
- Low Voltage Directive 2006/95/EC

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- BS EN 61326:1998 Electrical equipment for measurement, control and laboratory use - EMC requirements

Responsible Company:	RIGGTEK GmbH, Dissolution Test Systems Edelsbergstrasse 8-10 80686 München Germany
Product Type & Model:	SX8 – Sampilio X8
Product Classification:	Light Industrial
Product Functionality:	Dissolution Fraction Collector

A technical file for this equipment is retained at the above address.
This Declaration of Conformity was prepared according to EN ISO/IEC 17050-1:2004.

Signature of responsible person

Name of responsible person	Andreas Singer
Position of responsible person	Director
Place and Date of Issue	Munich, 19.11.2013

RIGGTEK Dissolution Test Systems

EC - DECLARATION OF CONFORMITY

CERTIFICATE NO. CE-DPX-20131119

We RIGGTEK GmbH, at address below, declare under our sole responsibility that the product detailed below to which this declaration relates complies with protection requirements of the following harmonized EC Directives:

- Machinery Directive 2006/42/EC
- Electromagnetic Compatibility Directive 2004/108/EC CE
- Low Voltage Directive 2006/95/EC

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- BS EN 61326:1998 Electrical equipment for measurement, control and laboratory use - EMC requirements

Responsible Company:	RIGGTEK GmbH, Dissolution Test Systems Edelsbergstrasse 8-10 80686 München Germany
Product Type & Model:	DPX – DissoPrep X8 and X15
Product Classification:	Light Industrial
Product Functionality:	Dissolution Medium Service Station Preparation, Degassing, Dispensing

A technical file for this equipment is retained at the above address.
This Declaration of Conformity was prepared according to EN ISO/IEC 17050-1:2004.

Signature of responsible person

Name of responsible person	Andreas Singer
Position of responsible person	Director
Place and Date of Issue	Munich, 19.11.2013

RIGGTEK

WWW.RIGGTEK.COM