ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC-Attestation of Conformity

No. N8 08 02 63657 001

Holder of Certificate: **Charles River Laboratories GmbH**
Sandhofer Weg 7
97633 Sulzfeld
GERMANY

Product: **Analysis Equipment (Portable Test System)**

Model(s): **Endosafe PTS**

Parameters:

Rated Voltage:	12 Vdc
Rated Current:	5 A
Protection Class:	III

Tested according to: EN 61010-1:2001

This EC-Attestation of Conformity is issued on a voluntary basis according to the Low Voltage Directive 2006/95/EC relating to electrical equipment designed for use within certain voltage limits. It confirms that the listed equipment complies with the principal protection requirements of the directive. It refers only to the particular sample submitted for testing and certification. See also notes overleaf.

Test report no.: 028-71323158-000

Date, 2008-02-22

CE After preparation of the necessary technical documentation as well as the conformity declaration the required CE marking can be affixed on the product. Other relevant directives have to be observed.

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstrasse 65 · 80339 München · Germany

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC-Attestation of Compliance

No. E8N 08 02 63657 002

Holder of Certificate:	**Charles River Laboratories GmbH** Sandhofer Weg 7 97633 Sulzfeld GERMANY
Name of Object:	**Analysis Equipment (Portable Test System)**
Model(s):	**Endosafe PTS**
Description of Object:	Rated Voltage: 12 Vdc Rated Current: 5 A Protection Class: III
Tested according to:	EN 61326/A3:2003, tables 3 and 1 EN 61000-3-2:2006 EN 61000-3-3/A2:2005

This EC-Attestation of Compliance is issued according to the Directive 2004/108/EC relating to electromagnetic compatibility on a voluntary basis. It confirms that the listed apparatus complies with all essential requirements of the EMC directive and applies only to the sample and its technical documentation submitted to TÜV SÜD Product Service GmbH for testing and certification. See also notes overleaf.

Test report no.: 028-71323158-000

Date, 2008-02-22

CE After preparation of the necessary technical documentation as well as the conformity declaration the required CE marking can be affixed on the product. Other relevant directives have to be observed.

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Hinweise

Grundlage für die Zertifikatserteilung ist die Prüf- und Zertifizierordnung von TÜV SÜD Product Service.

Mit Erhalt des Zertifikates wird der Zertifikatsinhaber Partner im Zertifiziersystem von TÜV SÜD Product Service und anerkennt die jeweils gültige Fassung der Prüf- und Zertifizierordnung und der Geschäftsbedingungen.

Prinzipielle Voraussetzung für die Gültigkeit des Zertifikates:

– Gültigkeit der zitierten normativen Prüfgrundlage(n) ist gegeben

und zusätzlich bei Zertifikaten mit Berechtigung zur Verwendung eines Prüfzeichens bzw. bei Zertifikaten für QM-Systeme:

– Voraussetzungen für vorschriftsmäßige Fertigung werden eingehalten.

– Die Fertigungs- bzw. Betriebsstätten werden regelmäßig überwacht.

Please note

Certification is based on the TÜV SÜD Product Service Testing and Certification Regula-tions.

On receipt of the certificate the certificate holder becomes a partner in the TÜV SÜD Product Service certification system and recognizes the current version of the Testing and Certification Regulations and the Standard Terms and Conditions.

Requirements for the validity of the certificate in principle:

– Validity of the quoted test standard(s)

In addition for Certificates with the right to use a certification mark and for QM certificates:

– Conditions for an adequate manufacturing are maintained

– Regular surveillance of the facility is performed

Akkreditierungen / Accreditations

Deutschland / Germany

Geräte- und Produktsicherheitsgesetz (GPSG) /
Equipment and Product Safety Act (GPSG)

Europa / Europe

- Niederspannungsrichtlinie 73/23/EWG
- Spielzeugrichtlinie 88/378/EWG
- Richtlinie für aktive medizinische Implantate 90/385/EWG
- Richtlinie für Medizinprodukte 93/42/EWG
- Richtlinie für In-vitro-Diagnostica 98/79/EG
- Richtlinie für Gasverbrauchseinrichtungen 90/396/EWG
- Richtlinie für persönliche Schutzausrüstungen 89/686/EWG
- EMV-Richtlinie 89/336/EWG
- Richtlinie für Sportboote 94/25/EG
- Richtlinie für Maschinen 98/37/EG
- Richtlinie für Ex-Schutz Geräte 94/9/EG

- Low Voltage Directive 73/23/EEC
- Toys Directive 88/378/EEC
- Directive for Active Implantable Medical Devices 90/385/EEC
- Directive for Medical Devices 93/42/EEC
- Directive on In Vitro Diagnostic Medical Devices 98/79/EC
- Directive for Gas Appliances 90/396/EEC
- Directive for Personal Protective Equipment 89/686/EEC
- EMC Directive 89/336/EEC
- Directive for Recreational Craft 94/25/EC
- Directive for Machinery 98/37/EC
- Directive for Ex Safe Equipment 94/9/EC

- ENEC Agreement for luminaires

USA

- Nationally Recognized Testing Laboratory (NRTL) to 29 CFR 1910.7 by OSHA
- Accredited for FDA 510(k) Third Party Review
- Conformity Assessment Body to the MRA for Medical Devices; FDA QSReg Inspections, FDA 510(k) Third Party Review

Asien-Pazifik Region / Asia Pacific

- Recognized Certification Body to Electrical Products (Safety) Regulation; Hong Kong
- Konformitätsbewertungsstelle / Conformity Assessment Body to the MRA for Medical Devices; Australien / Australia
- Konformitätsbewertungsstelle / Conformity Assessment Body to the MRA for Medical Devices; Neuseeland / New Zealand

Weltweit / Worldwide

- NCB im CB-Scheme des IECEE / NCB in the CB Scheme of IECEE
- TÜV SÜD Product Service Mark für Produkte / TÜV SÜD Product Service Mark for products DAP-ZE-1213.00
- Zertifizierung von QMS / Certification of QMS TGA-ZQ-008/93-00
- Medizinprodukte nach / Medical Devices to EN 46003; ISO 13485/88; ZLG-ZQ-999.98.12-46

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