



Product Service

# CERTIFICATE

No. Q1N 07 12 27591 011

**Holder of Certificate:** ARKRAY Factory, Inc.  
1480 Koji, Konan-cho  
Koka, Shiga  
520-3306 JAPAN

**Certification Mark:**



**Scope of Certificate:** Design and Development, Production, Distribution and Servicing of Diagnostic Devices (IVD), Lancet and Lancet Holder, System for Self-testing of Blood Glucose, System for Self-testing of Blood Lactate  
In-Vitro Diagnostic Devices:  
In-Vitro Diagnostic Reagents,  
In-Vitro Diagnostic Test Kits, In-Vitro Diagnostic Analyzers/ Software used in Urinalysis, Hematological Testing, Biochemical Testing and Immunological Testing

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality system which meets the requirements of the listed standard(s). See also notes overleaf.

**Report No.:** TYOMQS73516078A

**Valid until:** 2010-11-30

**Date,** 2007-12-01

Reiner Krumme



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TÜV SÜD Product Service GmbH  
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Germany



Akkreditiert durch  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln  
und Medizinprodukten  
ZLG-ZQ-999.98.12-46



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**Applied Standard(s):** ISO 13485: 2003  
Medical Devices  
- Quality Management Systems -  
Requirements for regulatory purposes

**Facility(ies):**

ARKRAY Factory, Inc.  
1480 Koji, Konan-cho, Koka, Shiga, 520-3306  
JAPAN

ARKRAY, Inc.  
57 Nishi Aketa-cho, Higashi-kujo, Minami-ku,  
Kyoto, 601-8045 JAPAN

ARKRAY Global Business, Inc.  
689 Takanna-cho, Nakagyo-ku, Kyoto, 604-8153  
JAPAN

Kusatsu Factory  
7-5-6 Ogaki, Ritto, Shiga, 520-3024 JAPAN

ARKRAY Factory Shanghai, Inc.  
No. 72-1, 887 Zuchongzhi Rd, Zhangjiang  
High-Tech Park, Pudong, 201203 Shanghai,  
PEOPLE'S REPUBLIC OF CHINA

ARKRAY Infinity, Inc.  
1480 Koji, Konan-cho, Koka, Shiga, 520-3306  
JAPAN

ARKRAY Marketing, Inc.  
1-20-20 Yotsuya, Shinjuku-ku, Tokyo, 160-0004  
JAPAN

