

**TÜV Rheinland**  
**Product Safety GmbH**  
Am Grauen Stein, D-51105 Köln

**TÜV**  
**Rheinland**

# CERTIFICATE

for a

## Quality Management System

according to

DIN EN ISO 9001/08.94

DIN EN 46001/09.96

The TÜV Rheinland Product Safety GmbH hereby certifies, that the

**Manufacturer:** BCI International  
W238 N1650 Rockwood Drive  
USA Waukesha, WI 53188-1199

has established and maintains a quality management system. Conformance with the requirements of the standards has been audited.  
The manufacturer is subject to a yearly surveillance audit.

Registration no.: SY 9611618 01

Report no.: E 9613282 E 01

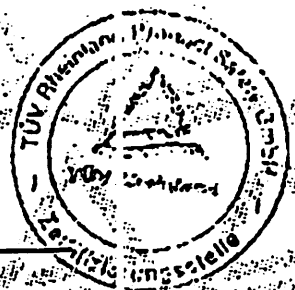
Date of expiry: 08.12.01

Scope: see attachment

Certification Body

Cologne, 09.12.96

*H. Peto Pap.*  
Dipl.-Ing. Pape





Page -1- of -1-  
Rev. 0

**TÜV Rheinland**  
**Product Safety GmbH**  
Am Grauen Stein D-51105 Köln

**Attachment to certificate**

**Certificate No.:** HD 9611617 01  
**Report No.:** E 9613282 E 01

**COPY**

**Manufacturer:** BCI International  
W238 N1650 Rockwood Drive  
USA Waukesha, WI 53188-1199

**Scope:**

Design, development, production and servicing of  
Handheld Pulse Oximeters  
Medical Gas and Vital Signs Monitoring Equipment

Cologne, 09.12.96



Notified Body

*[Signature]*  
Dipl.-Ing. Pape

**APPROVAL**

**EC Directive 93/42/EEC Annex II, Article 3**  
**Full Quality Assurance System**

**Registration No.:** HD 9611617 01

**Report No.:** E 9613282 E 01

**Manufacturer:** BCI International  
W238 N1650 Rockwood Drive  
USA Waukesha, WI 53188-1199

**COPY**

**Scope:** see attachment

**Date of Expiry:** 08.12.01

The Notified Body hereby authorizes the quality management system established and applied by the company mentioned above. This requirements of Annex II, Article 3 of the directive are met. This approval is subject to periodic surveillance, defined by Annex II, Article 5 of the aforementioned EC directive and can be used by the company with the manufacturer's declaration of conformity.

**Notified Body**

Cologne, 09.12.96



*[Signature]*  
Dipl.-Ing. Pape

**TÜV Rheinland Product Safety GmbH - Am Grauen Stein - D-51105 Köln**

Accredited by Zentralstelle der Länder für Sicherheitstechnik (ZLS) and  
Zentralstelle der Länder für Gesundheitsschutz bei Medizinprodukten (ZLG)

Notified under No. 0197  
to the EC Commission