BCI INTERNATIONAL

July 23, 1998

VIA FAX TRANSMITTAL
FAX NO.: 44 1535 635 582

Viamed
John S. Lamb
15 Station Road
Cross Hills
Keighley, West Yorkshire, RD20 7DT
England

Dear Mr. Lamb:

Thank you very much for your fax of yesterday. I understand that you are still in the process of CE marking your Flexible probes. As you will probably want to thoroughly test the Flexible probe with our Oxilink® to ensure compatibility, I will be sending you some samples of the three different sizes.

As you would be distributing the product throughout Europe, I would prefer to work with you directly instead of working through our distribution partner in each country. Please note that we do quite a bit of OEM business and do everything we can to ensure there is not any unnecessary competition between our OEM customers and our distributors.

Please find attached the information regarding our ISO-9001 Certification. At this time, we have not CE marked the Oxilink®. Our notified body is TUV Rheinland and they have indicated to us that it is not necessary. However, our Vice-President of Regulatory Affairs is able to CE mark it if a customer requires this to be done.

The prices for the Oxilink® will depend on the number of Oxilinks® shipped at one time. The Oxilinks® come in boxes of 10 or cartons of 100 pieces. Basically, the carton of 100 pieces consists of 10 boxes of 10. If the Oxilink® is purchased by the carton, then the price is $195.00/carton. If the Oxilink® is purchased in a box of 10, then the price is $22.00/box. Please note the Oxilink® come in sizes of small, medium, and large. The cartons of 100 cannot be mixed/matched with various sizes.

Please advise which of our other products you are interested in. It may be that I could have our UK distributor provide you with information on products that would be sold in the UK.

I look forward to hearing from you soon.

Best regards,

Meike Sorenson

Meike H. Sorenson
Regional Sales Manager
MHS/em

Att: ISO-9001 Certificate and TUV/MDD Certificate
VIA UPS: Oxilink® Samples

**BCI International**
W238 N1650 Rockwood Drive
Waukesha, WI 53188-1199 USA
Phone: 414/542-3100 Fax: 414/542-0718

TÜV Rheinland

# TÜV Rheinland Product Safety GmbH

Am Grauen Stein, D-51105 Köln

# 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

Dipl.-Ing. Pape

TÜV Rheinland



# 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

TÜV Rheinland Product Safety GmbH Zertifizierungsstelle

Notified Body

Dipl.-Ing. Pape

TÜV Rheinland

# 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

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

w/ Nellcor + CSI Y probes

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
1390 Piccard Drive
Rockville MD 20850

SEP 21 1995

Re: K953126
OxiLink, Disposable Oximeter Probe Cover
Dated: June 30, 1995
Received: July 5, 1995
Regulatory Class: II (two)
Product Code: 74 DQA

Mr. Donald J. Alexander
BCI International
W238 N1650 Rockwood Drive
Waukesha, Wisconsin 53188-1199

Dear Mr. Alexander:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

This letter immediately will allow you to begin marketing your device as described in your 510(k) premarket notification. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), promotion, or advertising please contact the Office of Compliance, Promotion and Advertising Policy Staff (HFZ-300) at (301) 594-4639. Other general information on your responsibilities under the Act

w/ Nellcor + CSI Y probes

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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