Graphic Controls LTD

DECLARATION OF CE CONFORMITY
DIRECTIVE 93/42/EEC

Graphic Controls Limited – St Peters Quay, Totnes, South Devon, UK TQ9 5XH.

Manufacture and distribute the following medical products and declare under their sole responsibility according to Annex VII for Class I products that the mentioned products meet the essential requirements of the Directive 93/42/EEC.

Class I products:

ECG-Electrodes –

REF: 4008140c, 4008142c, 4008143c, 4008144c, 4008145c, 4008146c, 4008147c, 4008148c, 4008149c 4008150c, 4008151c, 4008152c and 4008153c

All products are subject to the Quality Management system which is certified according to EN ISO 9001.

Products of Class I have the CE-mark.

The relevant documentation is maintained by Graphic Controls and is made available for inspection by the national authorities, the notified body and - where legally requested - by end-users and customers upon their request.

The validity of this Declaration of Conformity is in agreement with the validity period of the Quality Assurance Certificates of the notified body unless it is substituted by a new issue before this date.

GRAPHIC CONTROLS LTD.
ST. PETER'S QUAY
TOTNES, DEVON, TQ9 5XH
TEL: +44 (0) 1803 860100
FAX: +44 (0) 1803 863838

EC Certificate

TÜVRheinland®

Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60090920 0001

Report No.: 12022666 001

Manufacturer:
Kai Industries Co., Ltd.
1110 Oyana, Seki City
GIFU 501-3992
JAPAN

Products:
Surgical Blades, Scalpels, Biopsy Punches and
Micro Surgical Scalpels
(see attachment for products and sites included)

Replaces Approval, Registration No.: HD 60024932 0001

Expiry Date: 2018-12-19

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2014-01-07

Date: 2014-01-07

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Dipl.-Ing. S. Pane

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

LIETUVOS RESPUBLIKA Mažoji bendrija „Protingi medicinos sprendimai" VILNIUS

WEAVER
and company

565 Nucla Way, Unit B
Aurora, Colorado 80011-9319
1-800-525-2130
Phone 303-366-1804
Fax 303-367-5118
www.doweaver.com

EC Declaration of Conformity

We, the Manufacturer:

D. O. Weaver and Company (doing business as Weaver and Company)
565 Nucla Way, Unit B
Aurora, Colorado 80011 USA

declare under sole responsibility that the topical medical devices described below:

Nuprep® Skin Prep Gel
Ten20® Conductive Paste

are medical devices subject to Council Directive 93/42/EEC of June 14, 1993, amended by Directive 2007/47/EC of September 5, 2007, concerning medical devices, are Class I devices according to the classification criteria of Annex IX of the directive, Rule 1,
are non-invasive medical devices not intended as sterile devices,
do not perform a measuring function,
are therefore eligible for and conform with the conformity assessment procedure described in Annex VII of the directive, and
meet the essential requirements of Annex I of the Council Directive.

The initial date of the CE mark on Nuprep Skin Prep Gel and Ten20 Conductive Paste was June 1, 1998.

Authorized Representative:
Emergo Europe
Molenstraat 15
2513 BH The Hague
The Netherlands
+31 70 345 8570

C Cooper

Chris Cooper, CEO
Management with Executive Responsibility
D. O. Weaver and Company

4/13/2012
Date

LIETUVOS RESPUBLIKA
Mažoji bendrija
„Protingi medicinos sprendimai"
VILNIUS

PARKER LABORATORIES, INC.
286 ELDRIDGE ROAD, FAIRFIELD, NEW JERSEY 07004 U.S.A.

Declaration of Conformity

Manufacturer	Parker Laboratories Inc. 286 Eldridge Road Fairfield NJ 07004 USA

Parker Laboratories Inc. declares with sole responsibility that the CE marked products specified in the attached list meet the provisions of the Council Directive 93/42/EEC Concerning Medical Devices, including amendments through 2007/47EC.

Device Classification	Class I Non-Measuring, Non-Sterile
Conformity Assessment Route	Annex VII
EU Authorized Representative	Medical Device Safety Service (MDSS) GmbH Schiffgraben 41 D-30175 Hannover Germany

Mary Ann Hohensee
Quality Assurance Manager/Management Representative
Fairfield, NJ USA

March 15, 2010

Parker Laboratories Inc.

Notified Medical Device & UMDNS Description	UMDNS Code	Product	Part Numbers
Lubricating Jellies	12-401	Aquagel® Lubricating Gel	57-05, 57-20
Gel, Electrode	11-425	Spectra® 360 Electrode Gel	12-02, 12-08
		Signagel® Electrode Gel	15-60, 15-25
		Tensive® Conductive Adhesive Gel	22-60
		Redux® Electrolyte Gel	65-04
Media, Electroconductive		Signapad® Electrode Pad	16-40
		Signacreme® Electrode Cream	17-05, 17-20
		Signaspray® Electrode Solution and Skin Prep	18-25, 18-28, 18-04
		Redux® Electrolyte Cream	66-04
		Redux® Electrolyte Paste	67-05
Gel, Ultrasonic Coupling	15-321	Aquasonic®100 Ultrasound Transmission Gel	01-02, 01-08, 01-20, 01-34, 01-50
		Aquasonic® Clear Ultrasound Gel	03-02, 03-08, 03-34, 03-50, 03-54
		Aquaflex® Ultrasound Gel Pad	04-02
		Scan® Ultrasound Gel	11-08, 11-28, 11-28S
Ultrasonic Coupling Lotion		Polysonic® Ultrasound Lotion	21-08, 21-28, 21-50
Covers	15-571	Eclipse® Probe Cover	38-01, 38-03