



LABORATORIES, INC.

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

Doc. No.: CE-S-007

DECLARATION OF CONFORMITY
Medical Devices

We hereby declare that the distributed CE marked products specified in the annexed product list are covered by the "CE Marking of Conformity Certificate" reference number: 2005231CE01, renewed on March 31, 2009 and delivered by KEMA Quality B.V., Arnhem, The Netherlands, Notified Body Identification Number 0344, and conform to the required technical documentation, in accordance with Annex VII of the "EC-Directive", the Council Directive 93/42/EEC of 14 June 1993, concerning medical devices, including amendments through 2007/47/EC.

In addition, we ensure and declare that the distributed CE marked products, as mentioned and falling within Class IIa sterile, meet the provisions of the EC-Directive which apply to them.

This declaration is based on the application of the Quality System approved for the security and maintenance of the sterility of the products concerned, in accordance with Annex V of the EC-Directive.

This declaration is supported by the Quality System certification based on the harmonized standard ISO 13485:2003 Quality System Certificate with reference number: 11297.01 issued on August 28, 2009 and delivered by KEMA Quality B.V.

This Declaration of Conformity covers Aquasonic® 100 Sterile Ultrasound Transmission Gel as specified in the product list belong to this declaration, and is valid for all products concerned bearing the CE marking and manufactured at the follow site:

Manufacturer:

Parker Laboratories, Inc.
286 Eldridge Road
Fairfield, NJ 07004 U.S.A.

EU Authorized Representative:

Medical Device Safety Service GmbH
Schiffgraben 41
30175 Hannover, Germany


Mary Ann Hohensee
Quality Assurance Manager

January 4, 2010
Fairfield, NJ USA

Annex to the Declaration of Conformity

Parker Laboratories Inc.
286 Eldridge Road
Fairfield, NJ 07004 U.S.A

Doc. No.: CE-S-007-A-2

PRODUCT LIST

Aquasonic®100 Sterile Ultrasound Transmission Gel

This product list belongs to the Declaration of Conformity identified by CE-S-007 and specifies the CE marked products concerned that Parker Laboratories intends to distribute in conformity with the provisions of the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, including amendments through 2007/47/EC. The following list identifies the products by name, product code, lot number, and date of manufacture:

<u>Product name</u>	<u>Product code</u>	<u>Lot</u>	<u>Mfg. Date</u>
Aquasonic® 100 Sterile Ultrasound Transmission Gel	01-01	J41	October 2001
Aquasonic® 100 Sterile Ultrasound Transmission Gel (without overwrap)	01-01-4	J41	October 2001


Mary Ann Hohensee
Quality Assurance Manager

January 4, 2010
Fairfield, NJ U.S.A.