



Electro-Cap International, Inc.

DECLARATION OF CONFORMITY

We ELECTRO-CAP INTERNATIONAL, INC.

(supplier's name)

1011 WEST LEXINGTON ROAD, EATON, OHIO 45320 USA

(address)

declare under our sole responsibility that the product

ELECTRO-CAP SYSTEM OF ELECTRODE APPLICATION
(ELECTRO-CAP SYSTEM INCLUDES ALL ELECTRO-CAP MANUFACTURED ITEMS LISTED
ON THE PRICE SHEET DATED JANUARY 1, 2009 ATTACHED HERETO).

to which this declaration relates is in conformity with the following standard(s) or other normative document(s)

COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES

THE PRODUCT(S) IS A CLASS 1 NOT STERILE PRODUCT FOLLOWING ANNEX IX OF
MEDICAL EC DIRECTIVE 93/42/EEC

(if applicable) following the provisions of MEDICAL DIRECTIVE 93/42/EEC..... Directive
and in compliance with Directive 2007/47/EC.

NOTIFYING AGENT AND EUROPEAN AUTHORIZED REPRESENTATIVE FOR CE MARK RESPONSIBILITIES:

ELECTRO-CAP CENTER B.V.

POSTBUS 140

2420 AC NIEUKOOP, NETHERLANDS

TEL: 0172-572389

FAX: 0172-579659

EATON, OHIO USA

09/27/2011

(Place and date of issue)

ELECTRO-CAP INTERNATIONAL, INC.

BY:

(name and signature or equivalent marking
of authorized person)

WILLIAM N. HARDIN, PRESIDENT