

## EC DECLARATION OF CONFORMITY FOR CE MARKING (FOLLOWING THE PROVISIONS OF THE MEDICAL DEVICES DIRECTIVE 93/42/EEC)

Manufacturer Name: **Biosense Webster (Israel) Ltd.**Manufacturer Address: Einstein Building, 7 Etgar St.

P.O. Box 2009

Tirat HaCarmel 39120, Israel

EU Representative Name: Biosense Webster (Europe)

EU Representative Address: Johnson & Johnson Medical NV/SA

Dreve Richelle, 161 H 1410 Waterloo, Belgium

## CARTO XP system Version V8.1.74 (With SV-4700-04) Model FG-4700-00

Equipment Description	Catalog Number
CARTO XP Patient Unit	EM-4701-00
CARTO XP Communication Unit	EM-4702-00
CARTO XP Location Pad	EM-4703-00
Station kit	KT-4704-04
Workstation	CP-4066-00
Software kit	KT-4704-03
CartoMerge Kit	KT-4700-15
Accessories kit	KT-4700-01
Flat monitor	CP-4068-00
Flat monitor (alternate)	CP-4051-02

Product Classification: IIa, ANNEX IX, Rule 10

We, being the manufacturer, hereby declare that the Product(s) covered by this declaration conforms with the Essential Requirements, which apply to them (Annex I).

This declaration is supported by the following elements:

Technical file: TF-043-01 REv.2; Dated Feb. 10, 2005 with amendment 2 dated April 7, 2005.

CE Certificate of Quality Assurance (Annex II), Certificate No., CE 5428.01

Issued by TNO Certification; Notified Body Number 0336. Date of Issue: August 11, 2004

Date: April 26, 2005

Biosense Webster (Israel) Ltd.

Tirat HaCarmel, Israel

Israel A. Citron

Director, Quality & Regulatory Affairs and Business Excellence

This EC declaration of conformity replaces the previous declaration DC-4700-02 Rev 00G.