

Declaration of Conformity Certificate

We, Criticare Systems, Inc. ensure and declare with sole responsibility, that our medical devices: (see attached) meet the provisions of Council Directive 93/42/EEC (MDD) which apply to them.

Our medical devices have been classified as a Class IIB per rule 10 of Annex IX of the MDD.

The obligation as laid down in Annex II of the MDD 93/42/EEC and Swedish Regulation LVFS 2003:11 are fulfilled.

Annex II Certificate issued by: Intertek Semko AB
Certificate No.: 41314684

Our Representative in the European Union is:

MDSS GmbH
Schiffgraben 41
30175 Hannover
Germany

Signed this day 22 of December 2009



Alex Kaplan
Director Compliance/Regulatory Affairs

List of CE Products

<u>Product</u> -----	<u>Class</u> -----	<u>Rule</u> <u>(per MDD Annex IX)</u>	<u>Rationale</u> -----
503DX	IIb	10	1
504DX Series	IIb	10	1
504DXP-OBS (OBS 500)	IIb	10	1
506DXN Series	IIb	10	1
506N Series	IIb	10	1
506N3 Series	IIb	10	1
506DN/CN	IIb	10	1
507VV Series	IIb	10	1
8100 Series	IIb	10	1
8100E Series	IIb	10	1
8100E1 Series	IIB	10	1
8100H Series	IIb	10	1
8500	IIb	10	1
8500A	IIb	10	1
8500H	IIB	10	1
8500Q	IIb	10	1