

Edwards

EC Declaration of Conformity

Manufacturer: *Edwards Lifesciences LLC
One Edwards Way
Irvine, CA 92614, USA*

European Representative: *Dr. Robert Madjno
Edwards Lifesciences Services GmbH
Edisonstraße 6
85716 Unterschleißheim, Germany*

Product category: *Blood filtration equipment*

Product(s): ***Aquarius***

Classification: *Class IIb / Rule 11
(According to Annex IX of the MDD)*

Conformity Assessment Route: *Annex III & V*

UMDNS Nomenclature: *15039, Hemofiltration Units*

Applicable Standard(s) *Refer to Essential Requirements Checklist of
Technical File*

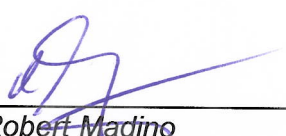
We herewith declare that the above mentioned products meet the provisions of the Council Directive 93/42/EEC of 14 June 1993 concerning Medical Devices. All supporting documentation is retained under the premises of the manufacturer.

The manufacturer has established and is maintaining a quality system which meets the requirements of DIN EN ISO 13485:2003

Notified Body: *TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 München, Germany
Identification Number 0123*

EC-Certificate: *G5 05 11 39555 117
(valid until 3 January 2011)*

Date: 30.03.2010
(valid until 3. January 2011)



*Dr. Robert Madjno
Director Regulatory Affairs Europe
Edwards Lifesciences Services GmbH*

Attachment

Aquarius – Software Versions:

REF: GE-F082-00	
Software Version 3.x	Date* / first Serial Number
3.06	27.09.2002 / 432
3.51	15.03.2004 / 938

REF: GE-F082-00	
Software Version 4.x "Platinum Software Platform 4"	Date* / first Serial Number
4.01	12.05.2004 / 971
4.01.10	23.12.2004 / 1194
4.01.11	23.12.2005 / 1466

REF: GE-F096-00 REF: GE-F097-00 REF: GE-F095-00 (Aquarius with Citrate Module)	
Software Version 6.x "Platinum Software Platform 6"	Date* / first Serial Number
6.00.00	25.01.2006 / 1503 - 1506
6.00.01	08.05.2006 / 1546 - 1577
6.00.02	27.06.2006 / 1578
6.01.00 machine production	15.06.2007 / 2030
6.02.04 software upgrade kit**	11.03.2010
6.02.04 machine production	17.03.2010 / 3335

* first production release date

** DMR release date

Aquarius – Software Versions - upgrades only:

Software Version 3.x	Date**
3.51.02	27.07.2005
3.52	13.03.2008

Software Version 4.x "Platinum Software Platform 4"	Date**
4.01.12	13.03.2008

** DMR release date