GAMBRO Renal Products

EC-Declaration of Conformity

We

Gambro Lundia AB Solution Division
Box 10101
SE-220 10 Lund
Sweden

being the manufacturer within the European Union of the following dialysis treatment device(s):

BiCart 1150 / 1250

declare that the above mentioned device(s) is/are in conformity with the relevant provisions of the Council Directive 93/42/EEC, concerning medical devices dated 14 June 1993, Annex I -Essential Requirements-, Annex IX -Classification criteria-, Annex XII -CE marking of conformity-, and our company has been subjected to the procedures laid down in Annex II -full quality assurance system- of the above mentioned directive under the supervision of the British Standards Institution, a Notified Body authorized by the United Kingdom Competent Authority, and carrying the Notified Body Number 0086.

All products of the above mentioned type(s) manufactured from 2001-12-26 are covered by this declaration.

This device does not incorporate, as an integral part, a substance as referred to in above mentioned Directive Annex I Section 7.4.

Lund, Sweden

Date: 2006-03-08

Stefan Knutsson