GAMBRO

EC-Declaration of Conformity

We

Gambro Dasco S.p.A. Sondalo Plant
Via Stelvio, 94
23035 Sondalo (SO)
Italy

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

Prismocitrate 10/2

declare that the above mentioned device(s) is/are in conformity with the relevant provisions of the Council Directive 93/42/EEC as amended by Directive 2007/47/EC, 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.

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

This declaration covers all products of the above-mentioned types manufactured from 2005.

Sondalo/Italy Date: 2010.07.07

Dr. Giuseppe Sasso
Plant Manager
(Manager with executive responsibility)