

# 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):

## **Anticoagulant Solution**

**Anticoagulant Solution used in extra corporeal circuits during the chronic or intensive care treatment according to the Technical file DD 011**

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.

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 covered all products of the above-mentioned types manufactured from 2005

Sondalo, Italy

Date: September 07<sup>th</sup>, 2005

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

