

EC-Declaration of Conformity

We

Gambro Dasco S.p.A Sondalo Plant
Via Stelvio, 94
230 35 Sondalo (SO)
ITALY

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

SelectBag Citrate

GMDN code and term: 35849 – Dialysate, Hemodialysis

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.

Sondalo, Italy

Date: 2018-07-28

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

