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Manufacturer's Declaration of Conformity

Australian Therepeutic Goods (Medical Devices) Regulations 2002
Full Quality Assurance Procedure

This is a declaration made in accordance with the requirements of Clause 1.8 of the Schedule 3 of the Australian Therapeutic Goods (Medical Devices) Regulations 2002 relating to the medical devices as described below.

Manufacturer's name:	**Gambro Dasco S.p.A. Sondalo Plant**
Business address:	**Via Stelvio, 94** **IT 23035 Sondalo (SO)** **Italy**
Medical device:	**Hemosol B0, Prismasol 2, Prismasol 4, Prism0cal Dialysis fluids for Acetate and/or Lactate and/or Bicarbonate dialysis according to the Technical File, TF-SO-014.**
Classification:	**Class IIb (see Annex 5 in TF-SO-014)**

GMDN Code and Term: 35849 – Dialysate, Hemodialysis

Scope of application: This declaration covers all products manufactured after 17 September 2001.
Each kind of medical device to which the Full Quality Assurance Procedures have been applied, complies with the applicable provisions of the essential principles, the classification rules, at each stage, from the design of the device until its final inspection before being supplied.
Assessment body: British Standards Institution, a Notified Body authorised by the United Kingdom Competent Authority, and carrying the Notified Body Number 0086.
Certificate Number: CE-01933.

This declaration does not include the kinds of medical devices, which would be selected for quality assurance assessment as required by THERAPEUTIC GOODS (MEDICAL DEVICES) REGULATONS 2002 (4.1.2).

Authorised signatory: Giuseppe Sasso, Plant Manager & QP Gambro Dasco Sondalo

Date: 2008-06-12

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Reference	Document or standard	Comment
ISO 13485	ISO 13485:2003 Medical devices – Quality management systems - Requirements for regulatory purposes	International
ISO 9001:2000	Quality management system	International
ISO 14644	Clean rooms and associated controlled environment. Part I - IV	International
ISO 14971	Application of risk management to Medical Devices	International
ISO 2859-1	Sampling procedure (Military standard)	International
MDD 93/42	Medical Device regulation	Europe