

CE-marked Product Code List to the MDR EU Declaration of Conformity

Business: Renal Care

Certificate Number:	G70 085480 0003 G12 085480 0004
Conformity Assessment Description/Annexes:	Annex IX
Device Risk Class:	Class III
Sterilization Method(s):	Gamma Irradiation
Sterilization Facility/Facilities:	IONISOS SAS Parc Dombes Côtière Activités 01120 Dagneux France IONISOS SAS ZA de L'Aubrée 72300 Sablé-sur-Sarthe France
Manufacturing Facility/Facilities:	Gambro Industries SAS 7 avenue Lionel Terray – BP 126 69883 Meyzieu Cedex France

Code/Catalog Number	Product or Trade Name	Intended Purpose/Use	Basic UDI-DI	STED Number and Revision	Date of initial MDR CE Marking
110654A	Evodial 1.0	Evodial hemodialyzers/ diafilters/ filters are intended to purify blood in hemodialysis, hemodiafiltration and hemofiltration.	008541200000000000000079JR.	STED-MDR-R-0064	12-Jan-2023
110653A	Evodial 1.3				
110652A	Evodial 1.6				
110651A	Evodial 2.2				

DocuSigned by:

This Product Code List has been reviewed and verified by: Carina Pforr Carina Pforr Date: 07-Feb-2023
(Name/Surname/Signature)

Title: Global Regulatory Lead