



Biogénesis[®]
we care about **life**

Declaration of Conformity

PRODUCT IDENTIFICATION		
Product name		Family
ECG and EKG Cables		BIOECG
Basic UDI-DI		EMDN
7730793BIOECGWX		Z10203020380
MANUFACTURER		
Name of Company	Address	Representative
Biogénesis S.R.L; SRN UY-MF-000002444	Divina Comedia 2043 Zip 11500, Montevideo Uruguay +598926017077 biogenesis@biogenesis.com.uy	Mr. Jorge Villardino
AUTHORIZED REPRESENTATIVE		
Name of Company	Country	Telephone/e-mail
CMC Medical Devices & Drugs S.L; SRN ES-AR-000000293	Spain	CMC Medical Devices & Drugs S.L C/Horacio Lengo N°18, zip 29006, Málaga-Spain Tel.: +3495121405, Fax.: +34952330100 info@cmcmedicaldevices.com
CONFORMITY ASSESSMENT		
Device classification	Route to compliance	
Class I Rule 1	Annex VIII of Medical Device Regulation (EU) 2017/745.	

Biogénesis S.R.L declares that the products in the abovementioned family meet the provision of the Council Directive Medical Device Regulation (EU) 2017/745. as transposed in the national laws of the Member States. A detailed list of product codes is provided in ANNEX A.

Company representative: Mr. Jorge Villardino

Title: Director

Date: 12/05/2021

Signature:



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Declaration of Conformity **Biogénesis - BIOECG** **Class I**

In compliance with:

EN ISO 13485:2016 - Medical devices — Quality management systems — Requirements for regulatory purposes

EN ISO 14971:2019 - Medical devices — Application of risk management to medical devices

EN ISO 15223-1:2012 Symbols for use in the labelling of medical devices

EN 1041:2008/A1:2013 Information supplied by the manufacturer of medical devices

EN ISO 10993-1:2009/AC:2010 - Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

EN ISO 10993-5:2009- Biological evaluation of medical devices - Part 5: Tests for *in vitro* cytotoxicity

EN ISO 10993-10:2009- Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

EN 60601-1:2006/A1:2013 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance



Declaration of Conformity

Biogenesis - BIOECG

Class I

ANNEX A

GMDN Code: 35562; Term: Reusable electrocardiographic lead set.

Biogenesis code	GMN code	Biogenesis code	GMN code	Biogenesis code	GMN code
BIOECG.ACC.AS	7730793300003	BIOECG.DR3.C5	7730793300638	BIOECG.MQ.RA.C3	7730793301260
BIOECG.ACC.P	7730793300010	BIOECG.DR3.S3	7730793300645	BIOECG.MQ.RA.C5	7730793301277
BIOECG.ACC.PP	7730793300027	BIOECG.DR3.S5	7730793300652	BIOECG.MQ.S10F	7730793301284
BIOECG.ACC.V	7730793300034	BIOECG.DR4.C5	7730793300669	BIOECG.MQ.S3F	7730793301291
BIOECG.ACC.VP	7730793300041	BIOECG.DR4.C6	7730793300676	BIOECG.MQ.S5F	7730793301307
BIOECG.AR.C3F	7730793300058	BIOECG.ED.P10F	7730793300683	BIOECG.MQ1.RA.C5	7730793301314
BIOECG.AR.C3F	7730793300065	BIOECG.ES.C3F	7730793300690	BIOECG.MQ2.3T	7730793301321
BIOECG.AR.P5F	7730793300072	BIOECG.ES.S3F	7730793300706	BIOECG.MQ2.5T	7730793301338
BIOECG.AR.S5F	7730793300089	BIOECG.FE.C5F	7730793300713	BIOECG.MQ2.C5	7730793301345
BIOECG.BC.3T	7730793300096	BIOECG.FE.S3F	7730793300720	BIOECG.MQ2.S3	7730793301352
BIOECG.BC.5T	7730793300102	BIOECG.FE.S5F	7730793300737	BIOECG.MQH.C5F	7730793301369
BIOECG.BC.C3D	7730793300119	BIOECG.FU.P10F	7730793300744	BIOECG.MQX.AC3	7730793301376
BIOECG.BC.C3F	7730793300126	BIOECG.FU2.S10F	7730793300751	BIOECG.NK.5T	7730793301383
BIOECG.BC.C3FN	7730793300133	BIOECG.HE.P10F	7730793300768	BIOECG.NK.C10F	7730793301390
BIOECG.BC.C5D	7730793300140	BIOECG.HP.P10F	7730793300775	BIOECG.NK.C10FN	7730793301406
BIOECG.BC.C5F	7730793300157	BIOECG.HP1.C3F	7730793300782	BIOECG.NK.P10F	7730793301413
BIOECG.BC.P5F	7730793300164	BIOECG.HP1.C5F	7730793300799	BIOECG.NK.S10F	7730793301420
BIOECG.BC.RA.S5	7730793300171	BIOECG.HP1.S3F	7730793300805	BIOECG.NK2.C10F	7730793301437
BIOECG.BC.S3D	7730793300188	BIOECG.HP1.S5F	7730793300812	BIOECG.NK2.P10F	7730793301444
BIOECG.BC.S3F	7730793300195	BIOECG.HP2.3T	7730793300829	BIOECG.NKA.C3F	7730793301451
BIOECG.BC.S5D	7730793300201	BIOECG.HP2.5T	7730793300836	BIOECG.NKA.S3F	7730793301468
BIOECG.BC.S5F	7730793300218	BIOECG.HP2.C3D	7730793300843	BIOECG.NKT.3T	7730793301475
BIOECG.BI.C3F	7730793300225	BIOECG.HP2.C3F	7730793300850	BIOECG.NKT.5T	7730793301482
BIOECG.BI.C5F	7730793300232	BIOECG.HP2.C3FN	7730793300867	BIOECG.NKT.C3F	7730793301499
BIOECG.BI.S5F	7730793300249	BIOECG.HP2.C5D	7730793300874	BIOECG.NKT.C3FN	7730793301505
BIOECG.BIT.C3F	7730793300256	BIOECG.HP2.C5F	7730793300881	BIOECG.NKT.C5D	7730793301512
BIOECG.BIT.S5F	7730793300263	BIOECG.HP2.S3D	7730793300898	BIOECG.NKT.C5F	7730793301529
BIOECG.BIT2.S3F	7730793300270	BIOECG.HP2.S3F	7730793300904	BIOECG.NKT.S3F	7730793301536
BIOECG.BL.C5F	7730793300287	BIOECG.HP2.S5F	7730793300911	BIOECG.NKV.C3F	7730793301543
BIOECG.BL2.C5F	7730793300294	BIOECG.HP3.C3F	7730793300928	BIOECG.NKV.S5F	7730793301550
BIOECG.BL2.S3F	7730793300300	BIOECG.HP3.S3F	7730793300935	BIOECG.PC.3T	7730793301567
BIOECG.BP.S10F	7730793300317	BIOECG.IT.IC	7730793300942	BIOECG.PC.5T	7730793301574
BIOECG.BP.S7F	7730793300324	BIOECG.ITH.P10F	7730793300959	BIOECG.PC.C10F	7730793301581
BIOECG.BT.P10F	7730793300331	BIOECG.JT.S10F	7730793300966	BIOECG.PC.C3F	7730793301598
BIOECG.BU.P10F	7730793300348	BIOECG.JT1.P10F	7730793300973	BIOECG.PC.P10F	7730793301604
BIOECG.BU2.P10F	7730793300355	BIOECG.JT1.S10F	7730793300980	BIOECG.PC.S10F	7730793301611
BIOECG.CA.P10F	7730793300362	BIOECG.KO.S5F	7730793300997	BIOECG.PC.S3F	7730793301628
BIOECG.CA2.P5F	7730793300379	BIOECG.MI.3T	7730793301000	BIOECG.PC.S5F	7730793301635
BIOECG.CA2.S10F	7730793300386	BIOECG.MI.5T	7730793301017	BIOECG.RA.C3	7730793301642
BIOECG.CAR.P10F	7730793300393	BIOECG.MI.C3F	7730793301024	BIOECG.RA.C5	7730793301659
BIOECG.CLICK.5	7730793300409	BIOECG.MI.C3FN	7730793301031	BIOECG.RA.C5N	7730793301666
BIOECG.CO.S5F	7730793300416	BIOECG.MI.C5D	7730793301048	BIOECG.RA.S3	7730793301673
BIOECG.CP.P10F	7730793300423	BIOECG.MI.C5F	7730793301055	BIOECG.RA.S5	7730793301680
BIOECG.CP.S10F	7730793300430	BIOECG.MI.P10F	7730793301062	BIOECG.RA.S7	7730793301697
BIOECG.CR.IC	7730793300447	BIOECG.MI.S3F	7730793301079	BIOECG.SC.C10F	7730793301703



BIOECG.DA.C3F	7730793300454	BIOECG.MI.S5F	7730793301086	BIOECG.SC.P10F	7730793301710
BIOECG.DA.C5F	7730793300461	BIOECG.MI3.IC2	7730793301093	BIOECG.SC.S10F	7730793301727
BIOECG.DA.S3F	7730793300478	BIOECG.MK.C3F	7730793301109	BIOECG.SC2.C10F	7730793301734
BIOECG.DA.S5D	7730793300485	BIOECG.MK.C5F	7730793301116	BIOECG.SC2.P10F	7730793301741
BIOECG.DA.S5F	7730793300492	BIOECG.MK.S5D	7730793301123	BIOECG.SP.C3F	7730793301758
BIOECG.DE.C5F	7730793300508	BIOECG.MKD.S3F	7730793301130	BIOECG.SP.C5F	7730793301765
BIOECG.DI.C10F	7730793300515	BIOECG.MM.P10F	7730793301147	BIOECG.SP.C5FN	7730793301772
BIOECG.DI.P10F	7730793300522	BIOECG.MM.P11F	7730793301154	BIOECG.SP.S3F	7730793301789
BIOECG.DI1.P10F	7730793300539	BIOECG.MO.C10F	7730793301161	BIOECG.SP.S5D	7730793301796
BIOECG.DR.3T	7730793300546	BIOECG.MO.P10F	7730793301178	BIOECG.SP.S5F	7730793301802
BIOECG.DR.C3F	7730793300553	BIOECG.MO.RA.P10	7730793301185	BIOECG.WA2.C10F	7730793301819
BIOECG.DR.C5F	7730793300560	BIOECG.MQ.3T	7730793301192	BIOECG.WA2.C10F	7730793301826
BIOECG.DR.MMT	7730793300577	BIOECG.MQ.5T	7730793301208	BIOECG.WA2.P10F	7730793301833
BIOECG.DR.MMT2	7730793300584	BIOECG.MQ.C10F	7730793301215	BIOECG.WA2.S10F	7730793301840
BIOECG.DR.S3F	7730793300591	BIOECG.MQ.C3F	7730793301222	BIOECG.ZO.C10F	7730793301857
BIOECG.DR1.RA.C5	7730793300607	BIOECG.MQ.C3FN	7730793301239	BIOECG.ZO.P10F	7730793301864
BIOECG.DR3.C3	7730793300614	BIOECG.MQ.C5F	7730793301246	BIOECG.ZO.S10F	7730793301871
BIOECG.DR3.C3N	7730793300621	BIOECG.MQ.P10F	7730793301253	BIOECG.ZO2.C10F	7730793301888

