

Technical Documentation	ECG Electrodes	DOCUMENT: 3-33-06 § 07.01
	DECLARATION OF CONFORMITY	REVISION: 1.0
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EU Declaration of Conformity

We declare that the Medical Device product family
ECG Electrodes
 is in conformity with the European Medical Device Regulation 2017/745 and with the consolidated version of Directive 2011/65/EU (RoHS)

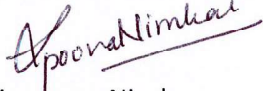
The Product Family "Disposable Physiological Monitoring Electrodes" is designed, produced, and verified under control of a quality system in accordance with ISO 13485:2016 and Annex IX of the Medical Device Regulation.

General Product Family Name:	ECG Electrodes
Directive Classification No:	Class 1
Conformity Assessment MDR Annex:	Annex VIII, Chapter III, Rule 1
GMDN Code:	35035
EMDN Code:	C020501
Basic UDI-DI	009336ECG-ElecSD

Manufacturer:
 SRN: US-MF-000012773
 Graphic Controls Acquisition Corp
 DBA Nissha Medical Technologies
 400 Exchange St.
 Buffalo, NY 14204

European Authorized Representative:
 SRN : FR-AR-000009795
 Nissha Medical Technologies SAS
 23-25 Boulevard de la Paix
 95800 Cergy
 FRANCE
 0033 1 39 72 66 66

This Declaration of Conformity is issued under the sole responsibility of Graphic Controls Acquisition Corp d.b.a Nissha Medical Technologies for the products listed below.


 Apoorva Nimkar
 Regulatory Affairs Coordinator

19-March-2025
 Date
 (Buffalo, NY, USA)

NISSHAMEDICAL.COM

Global Headquarters: 400 Exchange Street, Buffalo, NY 14204
 Phone: 716.853.7500 | Fax: 800.347.2420

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Please see the attached product list for reference

Product List

Part Number	Description
6503181V	108070
6503182V	108071
6503242V	590493
6503243V	590494
6500003V	A10000-60
6500004V	A10001
6500008V	A10003-4-60
6500009V	A10004-5
6500010V	A10004-5T
6500011V	A10004-60
6500012V	A10004-60T
6500013V	A10005
6500014V	A10005-1-60
6500015V	A10005-3-7%
6500016V	A10005-4NB
6500018V	A10005-60
6500019V	A10005-60-7%
6500017V	A10005-7%NB
6500481V	A10005-7NB
6500021V	A10005SG-60
6500022V	A10006-1-60S
6500001V	A10006-1-60TS
6500024V	A10006-5
6500026V	A10006-5RT
6500027V	A10006-5T
6500030V	A10007-5
6500032V	A10009

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6500033V	A10009-100
6500509V	A10009-100F
6500034V	A10011
6500037V	A10012-5S
6500040V	A10012-60S
6500038V	A10012-6S
6502923V	A10015-10S
6500043V	A10022
6500044V	A10023
6500046V	A10025-60
6500048V	A10026T-60
6502930V	A10027
6500049V	A10031-1-60
6500051V	A10031-60
6500052V	A10031-60RT
6500053V	A10032-1-60
6500054V	A10032-5
6500055V	A10032-60
6500057V	A10033-1-60
6500060V	A10040-60
6500061V	A10041-60
6500064V	A10042-60
6500065V	A10043
6500066V	A10049
6500070V	A10070-1-60
6500071V	A10070-5
6500072V	A10071-1-60
6500073V	A10072-1-60
6500603V	A10076
6500074V	A10083-3
6500076V	A10084-4
6502754V	A10096SG-30
6502779V	A10097-3

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6502764V	A10101-10
6500082V	A10201

DOCUMENT HISTORY

ISSUE	DATE	EDITOR	DESCRIPTION OF CHANGE
1.0	19-March-2025	Apoorva Nimkar	Initial Release

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