

EU Declaration of Conformity for Heart Sync Multifunction Electrodes	3-24-04	Attachment I
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EU Declaration of Conformity

We Declare that the medical device
Heart Sync Multifunction Electrodes
 are in conformity with the European Medical Device Regulation 2017/745 OF THE EUROPEAN
 PARLIAMENT AND OF THE COUNCIL of 5 April 2017
 on medical devices amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation
 (EC) No 1223/2009

The **Heart Sync Multifunction Electrodes** medical devices are designed, produced, and verified under control of a quality system in accordance to ISO 13485:2016, Annex IX of the Medical Device Regulation.

General Product Name:	SINGLE USE DEFIBRILLATOR PAD Heart Sync C-100 & Heart Sync T-100
Directive Classification No:	Class 1, non-invasive, Annex VIII, Chapter III, Rule 1
MDR Annex:	IV
Basic UDI-DI	009336Defib-Elec6F
Quality System is certified by:	Intertek Testing Services NA, Inc. 900 Chelmsford Street Lowell, MA, USA 01851

Manufacturer:
 Graphic Controls d.b.a Nissha Medical
 Technologies, Vermed, Biomedical Innovations
 400 Exchange St.
 Buffalo, NY 14204

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

The EU declaration of conformity is issued under the sole responsibility of Graphic Controls d.b.a Nissha Medical Technologies, Vermed, Biomedical Innovations for the following products:



MEDICAL TECHNOLOGIES

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See attached product list

Apoorva Nimkar
Regulatory Affairs Manager

20-may-2021

Date
(Buffalo, NY,USA)

Revision History			
Rev	Effective Revision Date	Description of change	Revised by
1	07-May-2021	MDR Remediation	Apoorva Nimkar

NISSHAMEDICAL.COM

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Product List

Product Description	Part Number
C100AC	6600014H
C100AC-PHILIPS	6600015H
C100AC-PHYSIO	6600017H
C100AC-ZOLL	6600019H
C100LOAC-PHILIPS	6600021H
C100LOAC-PHYSIO	6600022H
C100LOAC-ZOLL	6600023H
PED-100	6600063H
PEDIATRIC-PHILIPS	6600066H
PEDIATRIC-PHYSIO	6600068H
PEDIATRIC-ZOLL	6600070H
T100AC	6600090H
T100AC-PHILIPS	6600091H
T100AC-PHYSIO	6600093H
T100AC-ZOLL	6600095H
T100-CS	6600088H
T100LOAC	6600098H
T100LOAC-PHILIPS	6600099H
T100LOAC-PHYSIO	6600100H
T100LOAC-ZOLL	6600102H
T100LOAC-SCHILLER	6600263H
T100AC-SCHILLER	6600264H
T100AC-NIHONKOHDEN	6600265H
T100LOAC-NIHONKOHDEN	6600266H