



**U.S. FOOD & DRUG
ADMINISTRATION**

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Certificate No. 13968-9-2020

CERTIFICATE TO FOREIGN GOVERNMENT

In order to allow the importation of United States products into foreign countries, the U.S. Food and Drug Administration (FDA) certifies the following information concerning the product(s) to be exported listed below:

Name of Product(s)

See Attached List

(Two Pages)

Name of Manufacturer/Distributor, Address

See Attached List

(One Page)

The product(s) described above (and the manufacturing/distribution site(s) which produces/distributes it) is subject to the jurisdiction of the FDA under the Federal Food, Drug, and Cosmetic Act.

It is certified that the above product(s) may be marketed in, and legally exported from, the United States of America at this time. The manufacturing plant(s) in which the product(s) is produced is subject to periodic inspections. The last such inspection showed that the plant(s), at that time, appeared to be in substantial compliance with current good manufacturing practice requirements for the product(s) listed above.

Sincerely,

CDR Cesar A. Perez, PhD, Director
DRP2: Division of Establishment Support
Office of Regulatory Programs
Office of Product Evaluation and Quality
Center for Devices and Radiological Health
U.S. Food and Drug Administration, DHHS

This certificate is valid from September 10, 2020 to September 09, 2022.





**U.S. FOOD & DRUG
ADMINISTRATION**

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Certificate No. 13968-9-2020

Certificate to Foreign Government - Name of Manufacturer/Distributor Attachment Page 1 of 1

Manufactured for Owner Operator

ZOLL MEDICAL CORPORATION
269 MILL ROAD
Chelmsford, MA USA 01824

Name of Manufacturer

ZOLL MEDICAL CORPORATION
269 MILL ROAD
CHELMSFORD, MA USA 01824

BIO-DETEK, INC.
525 Narragansett Park Dr
PAWTUCKET, RI USA 02861

Name of Distributor

ZOLL MEDICAL CORPORATION
269 MILL ROAD
CHELMSFORD, MA USA 01824

---END OF MANUFACTURER/DISTRIBUTOR LIST----





Certificate No. 13968-9-2020

Certificate to Foreign Government - Name of Product(s) Attachment Page 1 of 2

Manufactured for Owner Operator

ZOLL MEDICAL CORPORATION
269 MILL ROAD
Chelmsford, MA USA 01824

Name of Manufacturer

ZOLL MEDICAL CORPORATION
269 MILL ROAD
CHELMSFORD, MA USA 01824

BIO-DETEK, INC.

525 Narragansett Park Dr
PAWTUCKET, RI USA 02861

Name of Distributor

ZOLL MEDICAL CORPORATION
269 MILL ROAD
CHELMSFORD, MA USA 01824

Name of Product(s)

ZOLL X Series Advanced
ZOLL AED 3
ZOLL AED 3 with Uni-padz
ZOLL AED 3 BLS Defibrillator
ZOLL D1400 Defibrillator
ZOLL PD1400 Pacemaker/Defibrillator
ZOLL 1600 Defibrillator
ZOLL 1700 Defibrillator
ZOLL D2000 Defibrillator
ZOLL PD2000 Pacemaker/Defibrillator
ZOLL M Series Defibrillator
ZOLL M Series with Rectilinear Bi-Phasic Option
ZOLL M Series SPO2 Option
ZOLL M Series 12SL Analysis Option
ZOLL M Series ETCO2 Option
ZOLL M Series NIBP Option
ZOLL M Series CCT with IBP Temperature Option
ZOLL E Series Defibrillator
ZOLL E Series with Real CPR Help
ZOLL E Series with See-Thru CPR
ZOLL E Series 12SL, Analysis Option
ZOLL E Series with Intubation Assist Option
ZOLL E Series with Bluetooth Dial Up Networking
ZOLL E Series with SPCO/SPMET Option
ZOLL E Series with CPR Ready Charge
ZOLL R Series Defibrillator
ZOLL R Series BLS Defibrillator
ZOLL R Series with NIBP and ETCO2 Options
ZOLL X Series Defibrillator
ZOLL AED Plus Defibrillator
ZOLL Fully Automatic AED Plus Defibrillator
ZOLL AED Pro Defibrillator
ZOLL Propaq MD DC Defibrillator (incl. paddles)
ZOLL Propaq M Cardiac Monitor
ZOLL One Step Electrodes
ZOLL One Step Basic Electrodes
ZOLL One Step Pacing Electrodes
ZOLL One Step CPR Electrodes





Certificate No. 13968-9-2020

Certificate to Foreign Government - Name of Product(s) Attachment Page 2 of 2

ZOLL One Step CPR (AA) Electrodes
ZOLL One Step Complete Electrodes
ZOLL One Step Pediatric Electrodes
ZOLL OneStep CPR II MFE Adult Multi-Function Electrode
ZOLL OneStep CPR Pediatric Multi-Function Electrode
ZOLL Radiolucent Solid Gel Electrodes
ZOLL Radiolucent Liquid Gel Electrodes
ZOLL Pro Padz Sterile Electrodes
ZOLL Pro Padz Bi-Phasic Electrodes
ZOLL Pedi Padz Solid Gel Electrodes
ZOLL Pedi Padz Radiolucent Electrodes
ZOLL Pedi Padz Pediatric Electrodes
ZOLL Pedi Padz II Electrodes
ZOLL Stat Padz Adult Multi-Function Electrodes
ZOLL Stat Padz II Electrodes
ZOLL CPR Stat Padz Electrodes
ZOLL Dura Padz Reusable Electrodes
ZOLL Dura Padz Gel Disposable Hydrogel
ZOLL CPR Dura-Padz Reusable Defibrillation Electrode with Dura-Padz Gel
ZOLL Pro Padz Electrodes
ZOLL Ready Padz Multi-Function Electrodes
ZOLL CPR-D Padz Electrodes
ZOLL PD2200 Multi-Function Electrodes
ZOLL Cardiology Specialty Electrodes
ZOLL Autoclavable Internal Handles Paddles
ZOLL Base PowerCharger 4x4 Battery Charger/Tester
ZOLL PowerCharger AC Power/Charge Module
ZOLL SurePower Charger Single bay charger
ZOLL Power Infuser Infusion Pump with Cartridges (M100B-3A)
ZOLL RescueNet Link Software-only product
ZOLL RescueNet 12-Lead Software-only product
ZOLL RescueNet ePCR Software-only product
ZOLL ePCR iOS Software-only product
ZOLL Code Writer Software-only product
ZOLL PocketCPR Cardiopulmonary Resuscitation Aid
731 Series Ventilators Model EMV, EMV+ (and EMV+ MRI), Eagle II (and Eagle II MRI),
AEV Continuous Ventilator, Z Vent, Z Vent MRI, and Z Vent Basic
Model 326/326M Aspirator, Model 324/324K Portable Aspirator
Model 330 Multifunction Aspirator

-----END OF PRODUCT LIST-----

