PROHLÁŠENÍ O SHODĚ

podle § 13 odst. 2 Zákona č. 22/1997 Sb. v platném znění o technických požadavcích na výrobky a o změně a doplnění některých zákonů a podle Nařízení vlády č. 181/2001 Sb.,
(dále jen zdravotnický prostředek)

Dovozce: **OMS – ZOLL s.r.o.,**
Sedliště ve Slezsku 384, 739 36
IČO: 465 803 79

prohlašuje, že u zdravotnických prostředků

Název:
Defibrilátory **PD 1400/D 1400**
Defibrilátory **PD 2000/D 2000**
Defibrilátory **Msérie/Msérie CCT**
Defibrilátory **Msérie/Msérie CCT s bifázickou defibrilací**
Defibrilátory **Msérie/Msérie CCT s měřením SpO2/CO2/12sv.EKG/NIBP/IBP/teploty**
Defibrilátory **AED Plus**
Defibrilátory **AED Pro**
Nabíjecí zdroj **AC**
Nabíječka baterií **4x4** a **1x1**
Multifunkční a stimulační elektrody ***pedi padz***
Multifunkční elektrody speciálně pro kardiologii ***pro padz***
RTG průhledné Multifunkční elektrody ***pro padz***
Bifázické Multifunkční elektrody ***pro padz***
Sterilní Multifunkční elektrody ***pro padz***
Stimulační elektrody ***pro padz***
Multifunkční elektrody, multifunkční elektrody ***stat-padz*** a ***stat padz II***
EKG elektrody
Elektrody ***CPR-D padz***
Autoklávovatelné interní elektrody

Výrobce: **ZOLL** Medical Corporation,
269 Mill Road, Chelmsford, MA 01824-4105, USA

Účel použití: terapeutické účely
Třída: II.b, III. (Interní elektrody)

bylo provedeno posouzení shody stanoveným postupem dle uvedených předpisů a že zdravotnický prostředek splňuje základní požadavky uvedené v těchto předpisech, je pro určený účel použití za obvyklých podmínek bezpečný a výrobce přijal opatření, kterými zabezpečuje shodu všech zdravotnických prostředků uváděných na trh s jejich technickou dokumentací a se základními požadavky.

Při posouzení shody byly použity:
technické přepisy: nařízení vlády č. 181/2001 Sb.,
jiné předpisy: Směrnice EU 93/42/EEC
technické normy: ČSN EN ISO 9001, ČSN-EN-46001

Pro posouzení bylo použito postupu dle přílohy II. Bod 3.2 s účastí autorizované osoby AO 202, Strojírenského zkušebního ústavu, s.p., Hudcova 56b, 621 00 Brno, č. rozhodnutí B-30-00807/01 ze dne 12.7.2001.

Bašová Jana

V Sedlištích 11.8.2005

Jana Bašová
jednatelka společnosti

Společnost byla zapsána do obchodního rejstříku dne 26.5.1992 u Krajského obchod. soudu Ostrava, oddíl C, vložka 3586.

DECLARATION OF CONFORMITY

We,

ZOLL *Medical Corporation*
269 Mill Road
Chelmsford, MA 01824-4105 USA,

declare under our sole responsibility that the products:

E Series
E Series Pulse Oximetry Option
E Series End Tidal CO_2 Option
E Series 12 Lead Option
E Series NIBP Option
M Series
M Series CCT
M Series Biphasic Option
M Series Pulse Oximetry Option
M Series End Tidal CO_2 Option
M Series 12 Lead Option
M Series NIBP Option
M Series IBP/TEMP Option
AED PLUS
AED PRO
CPR-D padz™
R Series

to which this declaration relates are in conformity with the provisions of Council Directive 93/42/EEC of 14 June 1993 of the Medical Device Directive which apply to them.

The quality system under which these products were designed and manufactured has been certified by TUV Rheinland Product Safety (0197) to be in compliance with Annex II of the Medical Device Directive including European Standard, ISO 13485.

18 OCT 2006

Paul Dias
V.P. Quality Assurance and Regulatory Affairs

ZOLL Medical Corporation

Authorized European Representative
Eric Rozeboom
ZOLL International Holding B.V.
Edisonring 3a
6669 NA Dodewaard
The Netherlands
Tel. +31 488-411-183

CE

9652-0076 REV YA

Certificate of Conformance

This is to declare under our sole responsibility that the following ZOLL Medical Corporation products:

AED Plus
AED Pro
E Series
M Series
M Series CCT
Smart Battery
Smart XL Battery
R Series
SurePower Battery

are in conformance with the provisions of Council Directive 2002/96/EC of 27 January 2003 on Waste Electrical and Electronic Equipment which apply to them.

ZOLL MEDICAL CORPORATION

UNITED STATES AND CANADIAN RETURNS

Important:
When your shipment arrives.....
Please inspect all cartons and count the number of pieces that you received. Verify numbers and items against the enclosed packing slip. Any discrepancies with your shipment must be brought to our attention within **10 working days.**

RETURN POLICY

The Return Authorization Number (RMA) must appear on the outside of all boxes along with a copy of the original packing slip indicating what products are being returned – failure to do so can cause a delay in processing your credit. Customer's using an RPS label must apply the return sticker to each package.

- Customer must obtain advance authorization for product returns from ZOLL. Returns received without proper authorization (RMA) will be returned to sender.

- Only product purchased within 90 days is eligible for return except electrodes, which need to be returned within 14 days.
  Capital Equipment returns must be authorized in advance by the Sales Representative and a RMA must be obtained from the ZOLL Customer Service Department, (800) 348-9011.

- If the equipment is not working properly, contact Technical Support at (800) 348-9011 or Tservice_master@zoll.com for troubleshooting. If the problem cannot be resolved, Technical Support will issue a service request number to authorize the return.

- Per OSHA standard on Blood Borne Pathogens (29 CFR 1910-1030) the customer is required to clean and disinfect all items returned.

How to Return a Product to ZOLL Medical

Obtain an RMA by calling the ZOLL Customer Service Department at (800) 348-9011.

1. Include a copy of the original packing slip indicating what product is being returned.
2. Insure that merchandise is well packaged for return to ZOLL Medical.
3. Write the return authorization number on the outside of the package.
4. Be sure to obtain a copy of the tracking label from your package.

How to Return Trade-In Equipment to ZOLL Medical

There is already an RMA created at the time of the sale. If you do not know what that number is, please call the ZOLL Customer Service Department at (800) 348-9011.

Please follow the instructions noted above for returning product to ZOLL Medical.

Cancellation

If the customer receives authorization from ZOLL Medical to return a product for credit the customer may be subject to a restocking charge of twenty (20) percent of the original list purchase price, but not less than $50.00 per product.

ZOLL MEDICAL CORPORATION

RETURN POLICY FOR PRODUCT SHIPPED INTERNATIONALLY
(Excluding Canada)

Important:
When your shipment arrives……..
Inspect all cartons and count the number of pieces received. Verify numbers and items against the packing slip that accompanied the shipment. Report any discrepancies immediately to your local salesperson or ZOLL distributor. A Return Material Authorization (RMA) number is required prior to sending any returns to ZOLL Medical.

An RMA number must appear on the outside of all boxes along with a copy of the packing slip indicating specific products that are being returned.

Returns received without an RMA number will be returned to the sender at the sender's expense.

RMA numbers are issued by the International Customer Service Department. The telephone number is 978-421-9655. Returns for capital equipment must be approved by the Vice President of International Operations prior to an RMA being issued.

If equipment is not working properly, contact ZOLL Technical Support at 978-421-9309 or TService_master@zoll.com **for troubleshooting. If the problem cannot be resolved, Technical Support will issue a Service Request Number to authorize the return.**

Per OSHA standard on Blood Born Pathogens (29 CFR 1910-1030) the customer is required to clean and disinfect all items returned.

HOW TO RETURN A PRODUCT TO ZOLL MEDICAL CORPORATION

1. **Obtain an RMA number.**
2. **Include a copy of the original packing slip indicating the items being returned.**
3. **Be sure the merchandise is well packaged for return to ZOLL Medical.**
4. **Write the RMA number on the outside of each package.**
5. **Keep a copy of the air bill reference for tracking purposes.**

CANCELLATION

If the customer receives authorization from ZOLL Medical to return a product for credit the customer may be subject to a restocking charge of twenty (20) percent of the original list purchase price, but not less than $50.00 per product.