



OSYPKA MEDICAL

Berlin, Germany • San Diego, California, USA

Osypka Medical GmbH • Grossbeerenstr. 184 • D-12277 Berlin

Osypka Medical GmbH

Grossbeerenstrasse 184  
D-12277 Berlin • Germany

We,

Telefon: +49 (30) 741 6058  
Telefax: +49 (30) 7479 2507  
E-Mail: mail@osypkamed.com

## Osypka Medical GmbH

Grossbeerenstrasse 184

12277 Berlin

Germany

declare under our sole responsibility, that the medical device

St. Jude Medical Model 3077  
External Single Chamber Pacemaker  
including accessories

is in conformity with the act on Medical Devices, the Medical Device Directive 93/42/EEC and the applicable standards and regulation.

This Declaration of Conformity covers all in our company manufactured loads of the above mentioned device, which are labelled with the CE mark.

This Declaration of Conformity is based on the Full Quality Assurance System certification with the registration number G1 05 05 39212 007 issued by the Notified Body Nr. 0123, the TÜV Product Service GmbH in Munich.

Berlin, June 22, 2005

Plant Manager

Quality Manager

Geschäftsführer: Dr.-Ing. Markus Osypka  
Registergericht: Berlin-Charlottenburg HRB 75797  
USt. (V.A.T.) ID: DE 136588220

Dresdner Bank AG Lörrach • Konto-Nr.: 6 604 079 00  
BLZ: 680 800 30 • SWIFT-BIC.: DRES DE FF  
IBAN: DE26 6808 0030 0660 4079 00

osypkamed.com