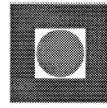


15 Declaration of Conformity

We,



OSYPKA MEDICAL

Berlin, Germany • San Diego, California, USA

Osyпка Medical GmbH
Albert-Einstein-Strasse 3
12489 Berlin

declare under our sole responsibility, that the medical device

External Single Chamber Pacemaker PACE 101H
including accessories

is in conformity with the act on Medical Devices, the Medical Device Directive 93/42/EEC amended by 2007/47/EC with reference to Directive 2006/42/EC on Machinery and the applicable medical device standards IEC 60601 - 1 and IEC 60601-2-31.

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 10 04 39212 013 issued by the Notified Body Nr. 0123, the TÜV Product Service GmbH in Munich.

Berlin, 2010/06/21

Dr.-Ing. Bernd Tröger
Plant Manager



Dipl.-Ing. (FH) Thilo Thümecke
Quality Manager

Vadybininkas
Andrius Markūnas

15. Atitikties deklaracija

Mes,



OSYPKA MEDICAL

Berlin, Germany • San Diego, California, USA

Osyпка Medical GmbH
Albert-Einstein gatvė 3
D-12489 Berlynas

Savo atsakomybe deklaruojame, kad medicininis prietaisas

Išorinis vienos kameros širdies stimuliatorius PACE 101 H su priedais atitinka Medicinos prietaisų direktyvos 93/42/EEC taikomos 2007/47/EC su nuorodomis į 2006/42/EC mechanizmams ir tam tikriems medicininų prietaisų standartams IEC 60601-1 ir IEC 60601-2-31

Ši atitikties deklaracija apima visus mūsų kompanijoje gaminamus aukščiau minimus prietaisus, kurie yra žymimi CE ženklu. Ši atitikties deklaracija paremta pilnos kokybės užtikrinimo sistemos sertifikavimu nr. G1 10 04 39212 013 išduotu notifikuotos agentūros Nr, 0123, TUV Product Service GmbH esnačios Miuniche.

Berlynas, 2010/06/21

(parašas)
Dr. Ing. Bernd Troger
Gamyklos direktorius

(parašas)
Dipl. Ing. Thilo Thumecke
Kokybės direktorius



2016-05-16



Vadybininkas
Andrius Markūnas