

CE Declaration of Conformity

Manufacturer : ONYX CZ, s.r.o.
Address : U sokolovny 567/60
635 00 Brno
Czech republic
Medical device : Portable syringe infusion pumps PPS 9001, PPS 9001S and its accessory equipment

We herewith declare that above mentioned portable syringe pumps are classified as Class IIb and comply with the EC Directive No. 93/42/EEC incl. amendments concerning medical devices.

This declaration is based on:

Certification according to Annex II of EC Directive No. 93/42/EEC incl. amendments concerning medical devices.

Certificate Number: MED 150156

Issued by: Electrotechnical testing institute, Prague, Czech republic, Identification No. 1014

Date: November 16, 2015

Standards:


EN 60601-1:1990+A1,A11,A12:1993+A2:1995+A13:1996

EN 60601-2-24:1998

EN 60601-1-2:2001

Place : ONYX CZ, s.r.o.
Brno

Date : November 27, 2015

Signature : 

Name : Antonín Žalkovský
Title : Quality Assurance Manager