

Declaration of Conformity

Y3HRT307Mx

Date: **February 2013**
Manufacturer's Name: **Dr. Sagie Bedwetting clinics Ltd.**
Manufacturer's Address: **72 Alexander Zaid st.,
26301 Haifa
Israel**
Equipment Under Test: **Stopee**

Compliance with the European directives **EMC & Safety: 2007/47/EC**

According to testing performed at SaYdos Ltd., the **Stopee** system was found in compliance with the **Safety** and the **EMC** requirements defined in the European generic standard EN60601-1: 3rd edition, which identifies the Safety, the Emission and the Immunity requirements for Medical equipment as follows:

EN60601-1-2 : 2007 3 rd edition	Medical Electrical Equipment
EN55011 : 2007	Class B Radiated and Conducted Emission
EN61000-4-2 : 2008	ESD : Contact Discharge $\pm 6\text{Kv}$ Air Discharge $\pm 8\text{Kv}$
EN61000-4-3 : 2008	Radiated immunity - 10V/m (80MHz-2500MHz)
EN61000-4-8 : 2009	Magnetic field 3A/m
IEC/EN60601-1: 3 rd edition	Requirements for the safety of – Medical devices

Results and test conditions of EMC & Safety tests are specified in "SaYdos Ltd." tests report No. Y3HRT307MC3, Y3HRT307SM3. We, the undersigned, hereby declare that the equipment tested at "SaYdos Ltd. LAB's" as specified above conforms to the requirements of above European Standards.

It is the manufacturer's responsibility to assure that additional production units of this model are manufactured with identical electrical and mechanical characteristics.



Tal Sagie
Dr. Sagie's Bedwetting Clinics Ltd.



Mr. Yossi Ben David M.sc
SaYdos Ltd. Lab Manager