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 3rd edition Medical Electrical Equipment
EN55011 : 2007 Class B Radiated and Conducted Emission
EN61000-4-2 : 2008 ESD: Contact Discharge ±6Kv
Air Discharge ±8Kv
EN61000-4-3 : 2008 Radiated immunity - 10V/m
(80MHz-2500MHz)
EN61000-4-8 : 2009 Magnetic field 3A/m
IEC/EN60601-1: 3rd 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

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