Ravimiamet
State Agency of Medicines

Mr. Vladimir Budarin
Indium-Top OÜ
Paldiski mnt. 68
10617 Tallinn, Estonia

August 08, 2007
No. MSO.-4/2606
Register of Medical Devices no:
INDT-INDI-7365

Notification on the registration of a new medical device

1. Estonian State Agency of Medicines has received documents concerning the following medical device produced by **Indium Top OÜ.**

   Salt nebulizer „Iiris"
   GMDN term: **nebulizer, <sodium chloride>**
   GMDN no: **12712**
   Risk class: **I**

2. The producer of the product mentioned in P.1, **Indium Top OÜ** (Trade Register no: 10588224) is registered in State Agency of Medicines.

3. The product has been issued a Declaration of Conformity by **Indium Top OÜ,** declaring, that the above mentioned product conforms with the essential requirements mentioned in Government of the Republic Regulation No 353 RTI 2004,85,580)

4. A medical device identified above has been added to **Estonian Register of Medical Devices**.

Yours sincerely

Andrei Knuut
Deputy Head of Medical Devices Department

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