

מדינת ישראל
STATE OF ISRAEL

Ministry of Health
Medical Technology and Infrastructure Administration
Medical Devices Department

משרד הבריאות
המינהל לטכנולוגיות רפואיות ותשתיות
אגף ציוד רפואי (אביזרים ומכשירים רפואיים)

Thursday, May 23, 2013

To Whom it May Concern

Please be advised that the Israeli Ministry of Health requires from all the manufacturers and importers of medical devices to issue a declaration confirming the registration of the devices and compliance with all required laws and regulations.

In addition to the signing of the declaration by the foreign manufacturer our guidelines for the registration of medical devices require the local importer to provide us with the following information:

1. *The relevant country/countries where the specific request is issued. (Only those countries: USA, Canada, New Zealand, Australia, UK, EU [please mention in what country])*

2. *Quantities of sales per country in the above mentioned country/ countries:*

- ☐ *Less than 50*
☐ *Between 50 to 200*
☐ *Between 200 to 1,000*
☐ *Between 1,000 to 10,000*
☐ *More than 10,000*
☐ *More than 100,000*
☐ *Millions*

3. *Whether the medical device is part of the national health coverage (reimbursement) in the countries where it is sold.*

Signature

It should be noted it is not feasible to import medical devices into Israel without the required information.

Sincerely yours,

N. Sheffer
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