

DESIGNATED AGENT AGREEMENT

The following is an agreement between _____, _____ (to be referred to as the “Company”) and mdi Consultants, Inc., (to be referred to as “**mdi**”), 55 Northern Blvd., Great Neck, NY 11021, USA, dated ____ of _____, 200__, for **mdi** to be designated as the Designated Agent (DA) as per the US Food and Drug Administration (FDA) requirements 21CFR Parts 207, 607 and 807 for foreign manufacturers who intend to or are importing medical devices, pharmaceuticals (human and/or animal) or biologics to the USA.

The agreement will commence on the date of receipt of a copy of this signed of the agreement along with the payment in full (for one year or three years) and a letter on the Company’s letterhead designating **mdi** as their designated agent.

It will be the responsibility of mdi as the company’s designated agent to perform the following tasks:

- keep an office address in the USA.
- to update the Company’s establishment registration and product listings forms.
- provide communications between the FDA and the Company, ie. upcoming inspections of the foreign site.

It will be the responsibility of the Company to provide the following information to mdi so that **mdi** can perform the above referenced tasks in accordance with the regulatory requirements:

- Provide mdi an update of changes to the Establishment registration (i.e. address, change in ownership, etc.)
- Notify mdi of any new products (devices or pharmaceuticals) for updated listings or changes to already listed products (i.e. dropping them from the product line.)
- Changes in telephone, fax or email address so that the lines of communication can be kept open.

The fee for the mdi to be your designated agent will be: (Please check one)

- _____ For one (1) year – US \$600.
_____ For three (3) years – US \$1500.

mdi Consultants, Inc.

As part of this program I will also be able to obtain use of mdi's consulting services at a reduced retainer rate.

Wiring instructions are as follows:

**Mellon Bank
One Mellon Bank Plaza
Pittsburg, Pa.
ABA#043000261
MELN US 3P
Credit to: Merrill Lynch
Account # 1011730
Further Credit to: MDI Consultants
Account # 849-07B79**

You will be notified 30 days prior to the end of your agreement term for renewal. This fee is non-refundable.

If any problems arise concerning the DA services, all communications should be made with the CEO of mdi to rectify the situation.

All information will be kept confidential.

**I fully understand the requirements of this agreement and my obligations and want to retain mdi Consultants, Inc. as our US FDA Designated Agent to comply with the FDA regulatory requirements that commence on _____, _____, 200 .
Day Month Year**

For: _____
Signature

print name and title

name of Company

address

city, state, code

date

For: _____
Signature

print name and title
**mdi Consultants, Inc.
55 Northern Blvd.
Great Neck, NY 11021**

date