FY 2004 MDUFMA Small Business Qualification Certification

Form Approved: [Pending]
Expiration Date: October I, 2004
OMB Statement: See reverse.

| Qualification Certification | O'IB Statement. See reverse. | | | | | |
|---|---|--|--|--|--|--|
| Section I — Information abou | ut Yourself | | | | | |
| 1. Name of entity claiming MDUFMA Small Business status: | 2. Federal Employer Identification Number: | | | | | |
| 3. Address where entity is physically located: | | | | | | |
| 4. Name of person making this Certification: | 5. Your telephone number: () Area Code Telephone Number | | | | | |
| 6. Your mailing address: ☐ Check (✔) if same as item | 7. Your e-mail address: | | | | | |
| 8. What is your relation to the entity claiming MDUFMA Small Bu | siness status? | | | | | |
| 9. Have you listed all of the entity's affiliates, partners, and parent | firms on the back (Section II) of this form? | | | | | |
| | e entity identified in item 1 no affiliates, partners, or parent firms | | | | | |
| 10. What types of medical device applications do you expect to sub- | omit during FY 2004? (Check one, or both.) | | | | | |
| ☐ Premarket application (BLA, PMA, PDP, PMR, or a supple | ment) □ 510(k) notification | | | | | |
| 11. Complete, sign, and date the following certification: | | | | | | |
| I certify that | | | | | | |
| Name of entity (must be identice) (Check <i>one</i> response:) Has no affiliates, partners, or parent firms. Has only the affiliates, partners, and parent firms listed on the second seco | | | | | | |
| (Check <i>one</i> response:) ☐ Reported "gross receipts or sales" of no more than \$30,00 return. I have attached a true and accurate copy of the entite ☐ Together with the affiliates, partners, and parent firms listed receipts or sales" of no more than \$30,000,000 on their Federal and accurate copy of the entity's most recent Federal income the most recent Federal income tax return of each of the entity. | ty's most recent Federal income tax return. on the back of this form, reported total "gross real income tax returns. I have attached a true tax return, and a true and accurate copy of | | | | | |
| I further certify that, to the best of my knowledge, the informatic Business Qualification Certification is complete and accurate. I under may subject me to criminal penalties under 18 U.S.C. 1001 and other certification is complete and accurate. | erstand that submission of a false certification | | | | | |
| Signature of person making this Certification: | | | | | | |
| Date of this Certification: | | | | | | |

| Section II — Information about Your Affiliates, Partners, and Parent Firms | | | | | | |
|--|---------------------------------------|-----------|----------------------------|--|----------|--|
| | b. Federal Employer Identification | | elation to E this Certi | d. Gross Receipts or Sales for Most-Recent | | |
| a. Name of Entity | Number (EIN) | Affiliate | Partner | Parent | Tax Year | |
| I | | | | | \$ | |
| 2 | | | | | \$ | |
| 3 | | | | | \$ | |
| 4 | | | | | \$ | |
| 5 | | | | | \$ | |
| 6 | | | | | \$ | |
| 7 | | | | | \$ | |
| 8 | | | | | \$ | |
| 9 | | | | | \$ | |
| 10 | | | | | \$ | |
| П | | | | | \$ | |
| 12 | | | | | \$ | |
| Total Gross Receipts and Sales of all Affiliates, Partners, and Parent Firms (Sum of lines 1 - 12) | | | | | \$ | |
| Gross Receipts and Sales of the Entity Making this Certification | | | | | \$ | |
| Total Gross Receipts and Sales Used to Determine Qualification as a MDUFMA Small Business (Sum of lines 13 and 14) | | | | | \$ | |
| and copies of your latest Federal income tax returns (including the latest returns of your affiliate, partner, and parent firms) to — | | | | on not verified | | |
| FY 2004 MDUFMA Small Business Qualification (HFZ-222) Division of Small Manufacturers, International, and Consumer Assistance 1350 Piccard Dr. | | | | (Decision must be "Does not qualify") Decision: Qualifies as a Small Business — | | |
| Rockville, MD 20850 | SBD-04 □ Does no | | | | | |

OMB Statement. The public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or another aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services Food and Drug Administration CBER, HFM-99 1401 Rockville Pike Rockville, MD 20852-1448

and to

Department of Health and Human Services Food and Drug Administration CDRH, HFZ-20 2098 Gaither Road Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number.