Inspection by Accredited Persons Program

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Overview

The Medical Device User Fee and Modernization Act of 2002 (MDUFMA) was signed into law on October 26, 2002. MDUFMA authorized the FDA to accredit persons for the purpose of conducting inspections of establishments that manufacture, prepare, propagate, compound, or process class II or class III devices. The owner or operator of such an establishment that is eligible may select an Accredited Person (AP), from the list below to conduct such inspections. On September 27, 2007, the Food and Drug Administration Amendments Act of 2007 (FDAAA) further amended this voluntary third-party inspection program by revising eligibility criteria.

Manufacturer Eligibility

To be eligible for inspection by an Accredited Person, a device establishment must meet the following conditions under section 704(g)(6)(A) of the Federal Food, Drug, and Cosmetic Act (the Act):

- The establishment's most recent inspection was classified by the FDA as No Action Indicated or Voluntary Action Indicated (see section 704(g)(6)(A)(i) of the Act).
- The owner or operator of the establishment submits a notice to the FDA that (see section 704(g)(6)(A)(ii)(I-IV) of the Act):
    - Provides the date of the last inspection and the classification of that inspection
    - States the intention of the owner or operator to use an Accredited Person to conduct inspections of the establishment
    - Identifies the particular Accredited Person, the owner or operator intends to select to conduct such inspection
    - Includes a certification that, with respect to the devices that are manufactured, prepared, propagated, compounded, or processed in the establishment –
        - At least 1 of such devices is marketed in the United States; and

- At least 1 of such devices is marketed, or is intended to be marketed, in 1 or more foreign countries, 1 of which countries certifies, accredits, or otherwise recognizes the person accredited and identified as a person authorized to conduct inspections of device establishments.

A device establishment intending to be inspected by an Accredited Person may contact the FDA at CDRH_Accredited_Persons_Inspection@fda.hhs.gov (mailto:CDRH_Accredited_Persons_Inspection@fda.hhs.gov) to determine eligibility.

List of Accredited Persons for Inspection

Manufacturers interested in participating in the program must select an Accredited Person (AP) from the organizations listed below in alphabetical order. Applications for accreditation under the Inspection by Accredited Persons (IAP) Program from these organizations have been evaluated by FDA's Third Party Recognition Board and have met the criteria published in the Federal Register on October 4, 2004 (69 FR 59250).

APs reflecting an asterisk have at least one inspector that has completed training and is currently qualified to conduct independent inspections under the IAP Program.

1. Firm Name: **Center for Measurement Standards/Industrial Technology Research Institute (CMS/ITRI)** *
   Address: **Bldg. 1, 321 Kuang Fu Rd., Sec. 2**
   City, State: **Hsinchu, Taiwan 30011**
   Country: **Republic of China**
   Contact Name: **Mr. Tzu-Wei Li**
   Phone: **+886 3 573 2227**
   Fax: **+886 3 573 4092**
   Email: **alberttwli@itri.org.tw** (mailto:alberttwli@itri.org.tw)
   Types of Devices: **All Medical Devices**

2. Firm Name: **DEKRA CERTIFICATION B.V.** *(formerly KEMA Quality B.V.)*
   Address: **Meander 1051**
   City, State: **Arnhem NL 6825 MJ**
   Country: **The Netherlands**
   Contact Names: **Mr. Harry Van Vugt, Third Party 510(K) Program Manager**
   Phone: **+31 88 96 83000**
   Fax: **+31 88 96 83100**
   Email: **medical.nl@dekra.com** (mailto:medical.nl@dekra.com)
   Types of Devices: **All Medical Devices**

3. Firm Name: **DQS Medizinprodukte GmbH**
   Address: **August Schanz Strasse 21**
   City, State: **60433 Frankfurt**
   Country: **Germany**
   Contact Name: **Szymon Kurdyn**
   Phone: **+49 (0) 69-95427-507, +49 (0) 69-95427-300**
   Fax: **+49 (0) 69-95427-388**
   Email: **szymon.kurdyn@dqs-med.de** (mailto:szymon.kurdyn@dqs-med.de)
   Types of Devices: **All Medical Devices**

4. Firm Name: **Presafe Denmark A/S**
   Address: **Tuborg Parkvej 8**
   City, State: **DK-2900 Hellerup**
   Country: **Denmark**
   Contact Name: **Mr. Ben Buus**
   Phone: **+45 3945 4999**
   Email: **bent.buus@dnvgl.com** (mailto:bent.buus@dnvgl.com)
   Types of Devices: **All Medical Devices**

5. Firm Name: **QS Zürich AG**
   Address: **P.O. Box 6335**
   City, State: **CH 8050 Zürich**
   Country: **Switzerland**
   Contact Name: **Mr. Lukas Beljean**
   Phone: **+41 1 350 46 65**
   Fax: **+41 1 350 46 69**
   Email: **info@quality-service.ch** (mailto:info@quality-service.ch)
   Types of Devices: **All Medical Devices, except IVDs**