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**NEWS RELEASE—For Immediate Release**

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**NEW SERVICE FROM FOREIGNEXCHANGE TRANSLATIONS HELPS  
IVD MANUFACTURERS MEET EUROPEAN REGULATIONS**

**Multilingual Compliance Process allows U.S. device manufacturers to achieve  
compliance with the European In Vitro Diagnostics Directive while  
reducing time-to-market and translation costs.**

**BOSTON, MA (August 17, 2001)**—With the European In Vitro Diagnostic Medical Device Directive 98/79/EC (IVDD) becoming mandatory in December 2003, IVD manufacturers are running out of time to get their devices in compliance.

And with each EU country requiring that all labeling and instructions for use be written in their local languages, IVD companies are faced with a daunting task. According to William Morton, President of Medical Device Consultants, Inc. (MDCI), “labeling is one of the more expensive and time-consuming things that a manufacturer will do to implement the directive.”

In response, ForeignExchange Translations, the recognized leader in translation services to regulated industries, has launched a proprietary service that helps IVD manufacturers comply with the IVDD while, at the same time, reduce translation costs and speed time-to-market.

“Our Multilingual Compliance Process focuses on the process, not just the language,” said Andres Heuberger, President of ForeignExchange Translations. “Its methodologies ensure successful IVDD implementation and result in reduced time-to-market, reduced costs, improved quality, and improved communications.”

The Multilingual Compliance Process relies on three stages to ensure the quality of the final product:

1. Compliance Translation Certification™
2. Control and Supervision
3. Tracking and Measurement

Within the framework of ForeignExchange's ISO 900X-compliant processes, the company tests and certifies all linguists working on IVD texts. Through a sophisticated quality-control mechanism, every step in the translation process is double-checked, following defined procedures and authorization levels. ForeignExchange monitors quality data and reports findings to its clients on a regular basis.

“To reduce costs, ForeignExchange's IVDD translation solutions are custom-tailored to the needs of each device manufacturer,” Heuberger added. “This includes the high-tech solutions—such as the latest computer-aided translation technology to leverage previously completed translation work—as well as low-tech solutions—streamlining review cycles, gaining economies of scale by bundling translation work, etc. With the Multilingual Compliance Process, translation and multilingual labeling expense becomes a predictable component of the entire in vitro diagnostic packaging effort,” concluded Heuberger.

“For IVD manufacturers, obtaining specialized translation services is one of the biggest challenges in completing the CE Marking process,” states MDCI's Morton. “ForeignExchange's robust processes provide the answer to IVDD translation compliance.”

### **About ForeignExchange Translations**

ForeignExchange Translations, Inc. is redefining the delivery of foreign-language services to regulated industries through a combination of superior customer service and reliable processes. ForeignExchange's solutions are based on its proprietary *Multilingual Compliance Process*, which combines expert linguists, best-of-breed technology, and measurable translation quality in a robust and scalable process that can be deployed in up to 32 languages simultaneously. The company provides technical translation, web globalization, and software localization solutions to clients such as Sigma Diagnostics (NASDAQ:SIAL), Guidant (NYSE:GDT), Honda (NYSE:HMC), Corning (NYSE:GLW), H&R Block (NYSE:HRB), and Beckman Coulter (NYSE:BEC). For more information, please visit [www.fxtrans.com/mcm.html](http://www.fxtrans.com/mcm.html).

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