



## **Information of Medical Device Conformity Assessment Body Service Provider**

(Should be filled in both **Chinese** and **English**)

### **1. Company Name:**

TÜV Product Service



### **2. Company profile:**

As global market leader in the medical device certification business, TÜV Product Service has awarded ISO9001, ISO13485 & CE certificates to more than 350 companies in P.R.C. and therefore takes a market share of 58%. TÜV Product Service is accredited for all three medical device directives and our experts, engineers, scientists and medical doctors are able to certify all products which require CE-mark - from well established and common products to the latest technology. Most high-tech devices, such as heart valves, dialysis equipment and dialysers or devices which include material of animal origin, carry the CE0123, which shows that TÜV Product Service is involved in product testing / design dossier review and auditing of the manufacturer. Most In-vitro Diagnostic Medical Device manufacturers located in P.R.C. are certified by TÜV Product Service.

In addition to the certifications based on ISO9001, ISO13485 & CE, TÜV Product Service is also maintaining intensive contacts to Medical Device authorities worldwide to ensure that our clients can get all their global approvals from one source. TÜV Product Service is authorized to perform 510(k) reviews for all eligible devices. These are about 80% of the 510(k) relevant product categories. So far we have performed more than 150 510(k) reviews under the US FDA Third Party Review Program.

We are authorized under the FDA Modernization Act to perform FDA inspections, fully recognized by the US FDA. However, we also offer audits based on the FDA regulations independent from the US FDA.

TÜV Product Service was the first organization to achieve accreditation as a CMDCAS registrar in the Canadian Medical Device Conformity Assessment System. Medical device manufacturers worldwide are using our CMDCAS auditors to obtain their CMDCAS certificate easily together with other approvals.

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Please note that the information provided by your company in this form may be used in the website of Hong Kong Medical and Healthcare Device Manufacturers Association ([www.medicaldevice.org.hk](http://www.medicaldevice.org.hk)). If you want to update the information in this form after the submission, you may send the updates by e-mail to: Dr. Theobald Chan, The Secretariat, HKMHDMA at: [theobald@medicaldevice.org.hk](mailto:theobald@medicaldevice.org.hk).



With more than 200 medical experts worldwide and more than 20 medical device auditors in P.R.C., TÜV Product Service is continuously providing the most competent and efficient service for its customers with not only certifications but also in-house and public training in compliance with the relevant international standards or aiming at internal auditors.

Within 10 years in P.R.C., TÜV Product Service has established a strong customer net with 80% global and local big players in the client list. With the corporate culture of “Competence, Certainty, Quality”, TÜV people are still devoting themselves to the best service to the customers...

### 3. Contact Information

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[www.tuvps.com](http://www.tuvps.com)