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**Regulatory affair agency:  
registration of medical devices in  
Ukraine**

## COMPANY PROFILE

RAA has more than 10 years experience in medical device regulation and can help you obtain medical device approval and start selling on Ukrainian market. We have successfully submitted applications for dozens of devices. We are the company that can offer operational efficiency, custom-tailored approach and reasonable prices for our service.

## OUR MAIN ACTIVITIES:

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### AUTHORIZED REPRESENTATIVE

With change of registration procedure on compliance assessment to technical regulations and appearance of such definition as AR in legislation we propose to assign RAA as independent, professional representative.

### REGULATORY CONSULTING

Market analyze, risk assessment, device classification and clinical reports. We guarantee and permanent work on to ensure your compliance with all national regulations. Our market is not Ukraine only but CIS, emerging markets also.

### MEDICAL DEVICE REGISTRATION

From start to end: the choice of compliance assessment route, preparing of technical file, permanent contact with regulatory authorities and state bodies to guarantee strict deadlines of your medical device approval.

### LOGISTICS OPERATIONS

Support or organizing of delivery and custom clearance of samples, finished medical devices for clinical investigations, tests carrying out or for batch/medical device verification.

### OTHER

We can provide registration of cosmetics, food additives. Gather, evaluate, organize, manage and collect information in a variety of formats. Write comprehensible, user-friendly, clear product information leaflets and labels.

