BUROTEC

BUROTEC HELPS TO MARKET YOUR MEDICAL DEVICES IN EUROPE.

Presence in the European Union

MEDICAL DEVICES

Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, United Kingdom.

info@burotec.es

(+34) 913 768 950 - 902 105 191
(+1) 954 478 5423

www.burotec.es

Av. Cardenal Herrera Oria 326 - A 28035 Madrid
16225 Park Ten Place – Suite 500, 77084 Houston

BUROTEC

MEDICAL DEVICES

SERVICES

· Initial Diagnosis Consultancy.
· Lab tests services.
· CE marking.
· Certification CE MDD.
· Regulation (EU) 2017/745 medical product.
· Regulation (EU) 2017/ 746 Diagnostic in vitro.
· Medical devices -Quality managment systems-.
· Partner for Representation services in EU.

(+34) 913 768 950 - 902 105 191
(+1) 954 478 5423

www.burotec.es

Av. Cardenal Herrera Oria 326 - A 28035 Madrid
16225 Park Ten Place – Suite 500, 77084 Houston

30 YEARS OF EXPERIENCE

BUROTEC

CE Marking for Medical Devices and for in vitro diagnostic Medical Devices

Due to Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746 on in vitro diagnostic medical devices, to market them in European Union, these devices must comply with CE Marking requirements.

DEFINITIONS AND CLASSIFICATION MEDICAL DEVICES

Any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

- Diagnosis, prevention, monitoring, prediction, prognosis, treatment, alleviation of disease or disability
- Investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,
- Providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations,
- Devices for the control or support of conception;
- Products specifically intended for the cleaning, disinfection or sterilization of devices as referred to in Article 1(4) and of those referred to in the first paragraph of this point.

Regulation (UE) 2017/745 shall also apply to the next list of groups of products without an intended medical purpose:

- Contact lenses or other items intended to be introduced into or onto the eye.
- Products intended to be totally or partially introduced into the human body through surgically invasive means for the purpose of modifying the anatomy or fixation of body parts with the exception of tattooing products and piercings.
- Substances, combinations of substances, or items intended to be used for facial or other dermal or mucous membrane filling by subcutaneous, submucous or intradermal injection or other introduction, excluding those for tattooing.
- Equipment intended to be used to reduce, remove or destroy adipose tissue, such as equipment for liposuction, lipolysis or lipoplasty.
- High intensity electromagnetic radiation (e.g. infra-red, visible light and ultra-violet) emitting equipment intended for use on the human body, including coherent and non-coherent sources, monochromatic and broad spectrum, such as lasers and intense pulsed light equipment, for skin resurfacing, tattoo or hair removal or other skin treatment.
- Equipment intended for brain stimulation that apply electrical currents or magnetic or electromagnetic fields that penetrate the cranium to modify neuronal activity in the brain.

Classification of medical devices shall be divided into classes I, IIa, IIb and III, taking into account the intended purpose of the devices and their inherent risks.

DEFINITIONS AND CLASSIFICATION IN VITRO DIAGNOSTIC MEDICAL DEVICE

Any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, piece of equipment, software or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information on one or more of the following:

- concerning a physiological or pathological process or state.
- concerning congenital physical or mental impairments.
- concerning the predisposition to a medical condition or a disease.
- to determine the safety and compatibility with potential recipients.
- to predict treatment response or reactions.
- to define or monitoring therapeutic measures.
- Specimen receptacles shall also be deemed to be in vitro diagnostic medical devices.

Classification of in vitro diagnostic devices shall be divided into classes A, B, C and D, taking into account the intended purpose of the devices and their inherent risks.

Burotec's experience

Burotec advises you so that your medical devices obtain the corresponding certification to be marketed in the European market.

Burotec is a Spanish company with 30 years of experience offering European regulatory consulting services. We are specialized in medical devices and In Vitro . We help companies to comply with regulatory obligations and quality.

Burotec is the company you need to certify your medical device and sell your product in Europe:

- Experience: We have been working in the sector for 30 years
- Knowledge: We are real experts in European regulation
- Experts: our team are qualified professionals who will make your project a success
- Methodology: We help you every step of the way, Permanent online consultancy and communication transparent.

What do we do?

MEDICAL DEVICES

• Initial Diagnosis Consultancy

- Medical device classification.
- Quality management System required.
- European Representative.
- Clinical trials required.
- Lab tests required.
- Notified Bodies.

• Lab test services

• Certification CE MMD

- Regulation (EU) 2017/745 medical product.
- Regulation (EU) 2017/ 746 Diagnostic in vitro.

• CE Marking

- Elaboration of Technical file:
  - Technical documentation.
  - Risks analysis.
  - Clinical trials.
  - Lab tests.
  - Harmonized Standards.
- Technical file processing with Notified body.

• Medical devices -Quality management systems-

- Requirements for regulatory purposes. ISO 13485:2016.

• Partner for Representation services in EU

- European Address.
- European phone number and email.
- Legal consultancy.
- Processing with European Official Departments.
- Representation and intermediation with Manufacturer´s European partners.