Universal Exports
Aktien Gesellschaft

Zug 23 July 2021

Ref.: The new rules on medical devices (Regulation (EU) 2017/745) and in vitro diagnostic medical devices (Regulation (EU) 2017/746)

To whom it may concern,

The transition from the registration of medical devices in the EU for non EU based companies will become more cumbersome in the years to come.
The switch from MDD & IVDD to MDR & IVDR will require high investments in regulatory procedures and documental management compared to today, and will increase over time.

There are, in our opinion, two approaches to this challenge:
1 - The first approach is to take on the challenge step by step solving problems as they arise.
2 - The second approach is to carefully plan for the present challenges but also for the future ones in a holistic way.

We believe in the holistic approach.

We believe that to be able to, successfully, overcome the regulatory challenges set by the EU Commission to non EU based medical devices producers, one must set up a legal entity in the EU.
A legal entity in the EU will allow the medical device producer to be treated as a “national company” and enjoy unhindered access to the EU market.

The set up of a new legal entity can be difficult and financially cumbersome or it can be efficient and easy.

We prefer the efficient and easy approach.

How?
Through a long standing network of well respected professionals, we are able to provide a one stop shop bundle solution.

We offer:
- Company incorporation
- Company domicile
- Management services
- Accounting services
- Legal services
- Regulatory assistance and NB relations management

All of the above is offered as an all inclusive yearly package (inclusive of basic service packages) for a length of 5 year, renewable for 5 year periods. Services are included in hourly packages, for the whole year, having the flexibility to add hours/services during the months where needed and reduce them to the package included minimum.

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Where?
We are set up to offer our package in Italy where the NB has decades of experience, charges reasonable fees and is efficient, reliable and globally respected and accepted.

Should you be interested in our solution and would like to receive a tailor made offer, get in touch with us.

Best Regards,

Universal Exports AG
Regulatory Services Team

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