Medical Devices Legal Framework in UK after Brexit

31 December, 2020

The United Kingdom leaves the European Union.

1 January, 2021

- CE Marking (MDD, AIMDD, MDR, IVDD, IVDR) is still recognized in Great Britain, but mandatory in Northern Ireland.
- UKCA Marking according to UK MDR 2002 available in GB (not recognized in NI).
- CE UKNI Marking according to EU laws is available and only recognized in NI.

- **UK Responsible Person (UKRP) mandatory for non-UK manufacturers**

- **Devices placed only in NI are to be registered with MHRA:** Applicable to those placed in NI:
  - Class I MDs
  - Custom Made MDs
  - General IVDs

For non-UK manufacturers, devices are to be registered by the UKRP

1 May, 2021

Devices placed in GB and/or NI are to be registered with MHRA:

- Class III MDs
- Class IIb implantable MDs
- AIMDs
- List A IVDs

For non-UK manufacturers, devices are to be registered by the UKRP

26 May, 2021

MDD and AIMDD no longer in force in the EU, consequently:

- **MDD and AIMDD no longer recognized in GB**.
- MDD and AIMDD no longer in force in NI. **MDR fully applicable in NI**.

1 September, 2021

Devices placed in GB and/or NI are to be registered with MHRA:

- Class IIb non-implantable MDs
- Class IIa MDs
- List B IVDs
- Self-test IVDs

For non-UK manufacturers, devices are to be registered by the UKRP

1 January, 2022

Devices placed only in GB are to be registered with MHRA:

- Class I MDs (unless already required by UK MDR 2002)
- General IVDs

For non-UK manufacturers, devices are to be registered by the UKRP

26 May, 2022

IVDD no longer in force in the EU, consequently:

- **IVDD no longer recognized in GB.**
- IVDD no longer in force in NI. **IVDR fully applicable in NI**.

1 July, 2023

UKCA mandatory in GB.
CE Marking no longer recognized in GB.

MDD: Medical Devices EU Directive 93/42/EEC
AIMDD: Active Implantable Medical Devices EU Directive 90/385/EEC
MDR: Medical Devices Regulation (EU) 2017/745
IVDD: In vitro Diagnostic Medical Devices EU Directive 98/79/EC
IVDR: In vitro Diagnostic Medical Devices Regulation (EU) 2017/746
UK MDR 2002: The Medical Devices Regulations 2002 (No. 618) as amended by the EU Exit Regulations

For further information:
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United Kingdom Responsible Person (UKRP)

What is a UKRP?

The UKRP is the point of contact between a manufacturer located outside the UK and the UK's Medicines and Healthcare products Regulatory Agency (MHRA).

What should you take into account while appointing a UKRP?

- The UKRP has to be established in the UK.
- A manufacturer can only have one single UKRP.

Although your distributor or importer located in the UK can act as your UKRP, as only one UKRP is allowed it will have to be responsible for all your devices (even if sold by other companies). Consequently, it is highly recommended to appoint a separate entity as your UKRP.

What are the responsibilities of a UKRP?

1. Ensures DoC and TD has been drawn up.
2. Ensures appropriate conformity assessment procedure has been carried out.
3. Keeps available a copy of DoC, TD and CE/UKCA Certificate (if applicable) for inspection by the MHRA.
4. Registers devices with the MHRA before the devices are placed on the UK market.
5. Should it be required by MHRA, provides with all necessary information and documentation (maybe even including samples – forward the request to manufacturer).
6. Cooperates with MHRA in any corrective/preventive action to mitigate the risk posed by devices.
7. Immediately informs manufacturer about complaints and reports from healthcare professionals/users/patients.
8. Terminates legal relationship if the manufacturer acts contrary to its obligations.

HOW CAN ASPHALION HELP YOU? ACTION PLAN

1

ASPHALION: your UKRP

You can appoint ASPHALION UK as your UKRP.
Through our office based in London, ASPHALION can act as your UKRP.

2

Decide your regulatory strategy for the UK Market

ASPHALION will help you figure out which is the best regulatory strategy for your company to comply with UK regulations according to the type of device, the regulatory status of your devices and the markets where you are currently selling the devices.

3

Make sure the devices comply with the applicable legal framework

ASPHALION will let you know if you must update your device´s Technical Documentation (TD) and if it is necessary to undergo a conformity assessment route with a third party (Notified Body and/or UK Approved Body).

Through our office in Spain, ASPHALION can guide you along the process of obtaining the CE Marking and/or UKCA Marking.

4

Device registration with the MHRA

Once the devices are compliant with the applicable legal framework, ASPHALION UK will proceed with the registration of your devices with the MHRA.

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