Master-Thesis/Masterarbeit

BREXIT

- Impact Analysis & Regulatory Strategy for placing Medical Devices on the UK market

The United Kingdom (UK) left the EU on January 31st, 2020. While Northern Ireland (NI) remained within the single European Union (EU) market, Great Britain (GB) left the single market and enforced its own rules for placing certain regulated goods (e.g. medical devices) on the market instead of accepting the CE marking from the EU.
The CE mark will continue to be required and accepted for medical devices sold in Northern Ireland whereas separate legislation will apply for Great Britain as of July 1st, 2023.

The UK Medicines and Healthcare products Regulatory Agency (MHRA) is developing its own medical device legislation based on the UK MDR from 2002 (which is mainly based on 93/42 EEC) and several amendments. On January 7th, 2022 no final consolidated legislation for Medical Devices was published.
The existing amendments show that, amongst other requirements, a UK specific device marking („UKCA"), a UK based legal representative, device registration with the MHRA and for certain device classes a UK Approved Body will be required by defined deadlines.

Figure 1: UKCA mark from www.gov.uk

Therefore, medical device manufacturers outside the UK need to adjust their regulatory market access strategies, their quality management system and have to update their device documentation and labeling in order to access or remain on the UK market with their medical devices.

The two main goals of this master thesis were:

1) Performing a gap analysis of the most recent UK medical device regulation compared to 2017/745 EU MDR with emphasis on:

   a. Differences in product specific requirements (e.g. UKCA vs. CE mark)

   b. Differences in the quality management system requirements with respect to the regulatory strategy

2) Developing a market access strategy for the UK (GB + NI) for medical devices manufacturers based in the European Union, this will include:

   a. Developing a template that covers the Essential Requirements of the UK MDR as well as Annex I of 2017/745 EU MDR

   b. Developing a Regulatory Strategy Plan template for R&D projects that covers the EU and UK market

This master thesis was developed in collaboration with Stryker Instruments- AGT as part of Stryker Leibinger GmbH & Co. KG based in Freiburg, Germany.

Keywords: BREXIT, UK MDR 2002, UKCA, UK Approved Body, EU MDR, 2017/745 EU, UK market access, UK responsible person, UKCA marking, MHRA, Great Britain, Medical Devices