Managing Brexit

A Practitioners Perspective

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About

Psephos was founded in 2001 and works with clients to bring medical technologies to market and maintain them on the market. We have a wide range of experience from class I to Class III devices as well as Digital Health, AI and Clinical Services. We provide Responsible Person and UKCA services for the UK market.

Jacques du Preez

- Co Founder of Psephos and founded and sold a medical device company
- Work with NHSX, DHSC, Regulatory lead for NHS Covid-19 App
- Advisor to Medtech companies in the UK, US, Europe and Asia.
- Broad and deep Medtech operational experience
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Look at this from the perspective of the manufacturer taking into account

- Brexit
- MDD, AIMDD, IVD
- MDR & IVDR

Introduction

From 1 January 2021 the Medicines and Healthcare products Regulatory Agency (MHRA) will take on the responsibilities for the UK medical devices market that is currently undertaken through the EU system.

There are different rules for

- Great Britain = England, Wales and Scotland
- Northern Ireland
- EU

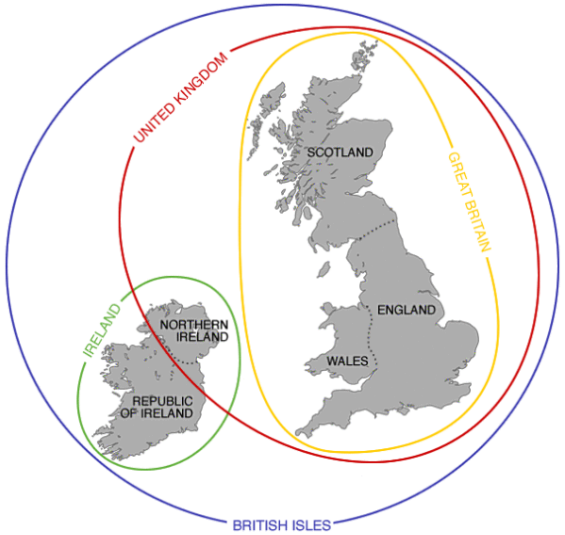
Current UK Legislation - Medical Devices Regulations 2002 (UK MDR 2002) will continue to have effect in Great Britain after the transition period and covers

- Directive 90/385/EEC on active implantable medical devices (EU AIMDD)
- Directive 93/42/EEC on medical devices (EU MDD)
- Directive 98/79/EC on in vitro diagnostic medical devices (EU IVDD)

Caveat: Subject to parliamentary approval, Brexit negotiations and further development

Great Britain

- CE marking will continue to be used and recognised until 30 June 2023
- CE Certificates issued by Notified Bodies will continue to be valid for the Great Britain market until 30 June 2023
- A new route to market and product marking will be available for manufacturers wishing to place a device on the Great Britain market from 1 January 2021 ie a **UKCA** conformity assessment route
- From 1 January 2021, all medical devices and in vitro diagnostic medical devices (IVDs) placed on the UK market will need to be **registered** with the MHRA. There will be a grace period for registering depending on your device class.
- If you are a manufacturer based outside the UK and wish to place a device on the UK market, you will need to establish a **UK Responsible Person** from 1 January 2021 who will take responsibility for the product in the UK



UKCA Marking

The UKCA mark will not be recognised in the EU, EEA or Northern Ireland markets

Manufacturers will be able to use the UKCA mark from 1 January 2021.

From 1 July 2023, to place a device on the Great Britain market, you will need to meet the requirements for placing a UKCA mark on your device.

This requirement will not apply to Northern Ireland traders.

- If you reduce or enlarge the size the letters must be in proportion
- At least 5mm in height
- Easily visible, legible

Responsible Person
1 January 2021

The UK Responsible Person will act on behalf of the outside-UK manufacturer including registering with the MHRA before the manufacturer's devices can be placed on the UK market. The Responsible Person will

- Ensure that the **declaration of conformity** and **technical documentation** have been drawn up.
- Ensure an appropriate **conformity assessment** procedure has been carried out by the manufacturer.
- Keep available **copies** for inspection by the MHRA of
  - Technical documentation,
  - Declaration of conformity and,
  - Relevant Certificates relevant certificate, including any amendments and supplements.
- Respond to **MHRA requests** and forward to the manufacturer MHRA requests for samples or access to a device, and **ensure** that the MHRA receives the samples or has access
- Cooperate with the MHRA on any preventive or corrective action (**CAPA**)
- Immediately **inform** the manufacturer about complaints from healthcare professionals, patients and users
- **Terminate** the legal relationship with the manufacturer if the manufacturer acts contrary to its obligations under these regulations, **inform** the MHRA and, if applicable, the relevant notified body of that termination.

Registering your Device with the MHRA

Currently only Class I devices register with the MHRA. This will change as off 1 January

The following devices, which are already registered or require to be registered with the MHRA - **no grace period**

- New and existing class I devices and general IVDs required to be registered with the MHRA

The following devices have **4 months** to register with the MHRA (until 30 April 2021):

- Active implantable medical devices
- Class III medical devices
- Class IIb implantable medical devices
- IVD List A

The following devices, have **8 months** to register with the MHRA (until 31 August 2021):

- Class IIb non-implantable medical devices
- Class IIa medical devices
- IVD List B
- Self-test IVDs

The following devices, have **12 months** to register with the MHRA (until 31 December 2021):

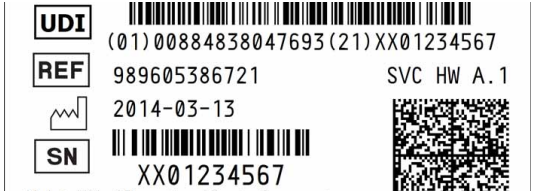
- Class I medical devices (registered with a competent Authority in the EU)
- General IVDs (registered with a competent Authority in the EU)

UK Conformity Assessment Bodies

From 1 January 2021, the MHRA will be able to designate UK Approved Bodies to conduct assessments against the relevant requirements for the purpose of the UKCA mark.

Existing UK Notified Bodies with designations under the MDD, IVDD or AIMDD will have their designations rolled over automatically (grand fathering) , without having to undergo a new designation process :

Labelling



As of 1 January 2021, medical devices placed on the Great Britain market will need to have either a UKCA mark or a CE mark, depending on which legislation the device has been certified under.

If you already have a valid CE mark on your device, **you will not be required to re-label the device with a UKCA mark until 1 July 2023** for placement on the Great Britain market.

However

For manufacturers outside of the UK you will be required to place details of your responsible person on the

- Label, or
- Outer packaging, or
- Instructions for use

Devices that are dual labelled with both the CE and UKCA marks will continue to be accepted on the Great Britain market after 1 July 2023.

Northern Ireland - UK(NI)

Under the terms of the **Northern Ireland Protocol** from 1 January 2021 rules rules for placing medical devices on the Northern Ireland market will differ from those applicable to Great Britain.

The Medical Device Regulations (2017/745) and the in vitro Diagnostic Medical Device Regulations (2017/746) will apply in Northern Ireland from 26 May 2021, and 26 May 2022 respectively

UK Approved Bodies will be able to conduct conformity assessments for the purposes of the Northern Ireland market.

Where a device has been assessed by a UK Approved Body, the **UK(NI)** mark will accompany, but not replace, the CE mark.

Products carrying both the CE mark and UK(NI) mark cannot be placed on the EU market.

UKCA marked devices will not be accepted on the Northern Ireland market unless accompanied by the CE or CE UK(NI) mark.

Call to Action

Great Britain Manufacturer selling to the EU

1. Appoint EU/NI based Authorised Rep
2. Appoint EU based Notified Body
3. Transition to the MDR (May 2021) and IVDR (May 2022)
4. Labelling changes to reflect EU/NI authorised rep
5. Register all devices with MHRA from 1 Jan 2021
6. Develop and implement UKCA strategy by June 2023 eg UK based Notified body & labelling

Call to Action

EU Manufacturer selling to Great Britain

- Appoint a UK Responsible Person
- Register devices with MHRA
- Update labelling to reflect UK Responsible Person
- Appoint UK based Notified Body for UKCA mark
- Develop and implement UKCA strategy by June 2023 eg UK based Notified body & labelling

Call to Action

ROW (Americas, Asia, Africa) Manufacturers selling to Great Britain

- Develop and implement UKCA strategy
- Appoint a UK Responsible Person
- Register devices with MHRA
- Appoint UK based Notified Body for UKCA mark
- Update labelling to reflect UK Responsible Person

What we Do for our Clients

psephos BIOMEDICA

Strategy

- Clinical Strategy
- Regulatory Strategy
- Quality Strategy
- Compliance Strategy

Regulation

- Medical Device Regulation Gap Analysis
- Technical File Preparation and Updates
- Device Registration
- CE Marking & Recertification
- FDA Approval
- UK Responsible Person
- UKCA Marking

Clinical

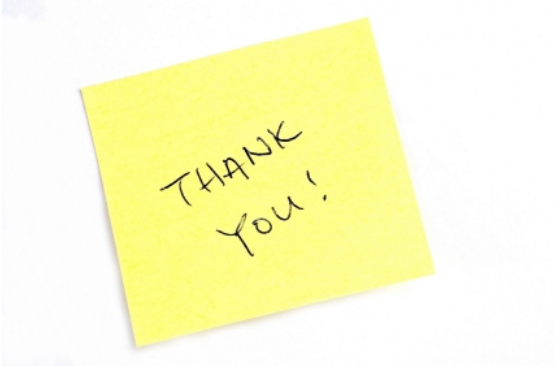
- Clinical Evaluation Reports
- Clinical Evaluation Plans
- Clinical Trial Strategy, Design and Management (ISO 14155)
- Post Market Clinical Follow-Ups (PMCF) including registries
- Post-Market Surveillance (PMS)

Quality

- ISO 13485 Quality Management Systems Development, Implementation and Compliance
- FDA QSR Quality Management Systems Development, Implementation and Compliance

Operations

- Risk Management – ISO 14971
- Product Development and Manufacturing
- Provision of Executive management and oversight
- Project Management



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