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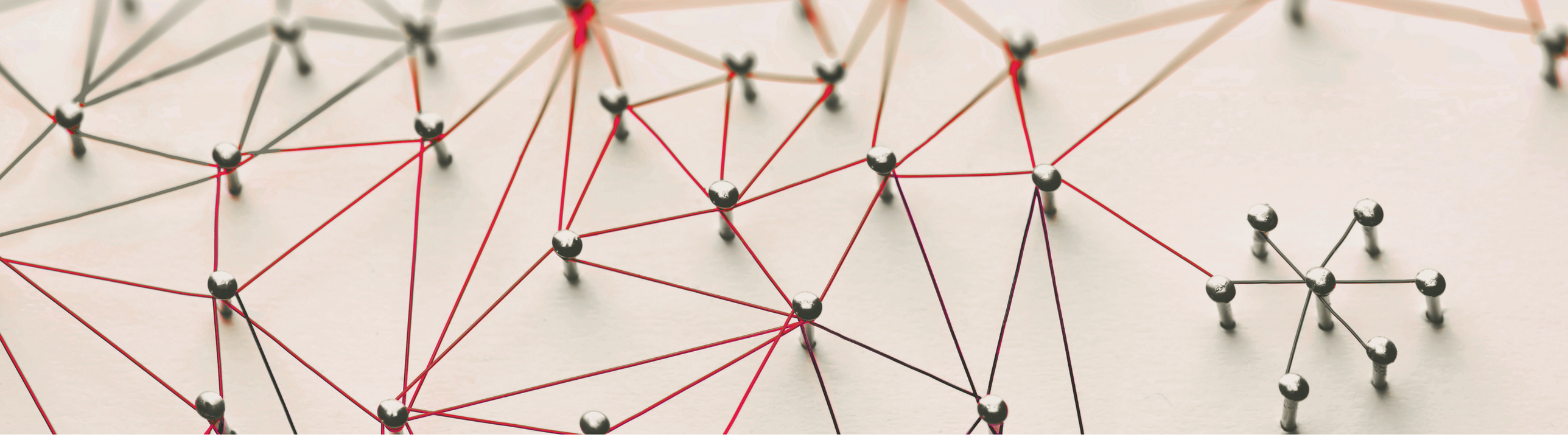
regulatory compliance worldwide

UK Responsible Person Services

UK Market Access for Medical Devices and IVDs



About confinis

confinis is a global consulting organization focused on medical devices, combination products, and IVDs. We provide expert advice to companies in the areas of regulatory compliance, quality systems, clinical evaluation and market access. We also have expertise in digital health, auditing and training.

Our business philosophy is based on helping businesses fill the gaps in their operations and achieve success.

confinis has a global network of consultants, able to offer solutions to the most complex business problems. Our global HQ is in Switzerland, but we also have facilities in Maryland, USA, and Cambridge, UK.

UK Market Access

Following the UK's departure from the European Union, the Government introduced new requirements for manufacturers wishing to place medical devices and IVDs on the UK market. The changes came into effect on January 1, 2021 and are as follows:

- Products must be registered with the MHRA and, depending upon classification, undergo a conformity assessment by a UK Approved Body to enable use of the new UKCA mark
- Overseas manufacturers must designate a UK Responsible Person to register their products with the Medicines and Healthcare products Regulatory Agency (MHRA).

confinis can assist with this process and is registered with the MHRA to provide UK Responsible Person services.

UK Responsible Person

The UK Responsible Person, as required by the UK Government, has several important roles and acts as the local link between manufacturers and the MHRA:

(a) ensure that the declaration of conformity and technical documentation have been drawn up and, where applicable, that an appropriate conformity assessment procedure has been carried out;

(b) keep available for inspection by the MHRA a copy of the technical documentation, a copy of the declaration of conformity and, if applicable, a copy of the relevant certificate, including any amendments and supplements;

(c) in response to a request from the MHRA, provide the MHRA with all the information and documentation necessary to demonstrate the conformity of a device;

(d) where they have samples of the device or access to the device, comply with any request from the MHRA to provide such samples or access;

(e) where they have neither samples of the device nor access to the device, communicate to the manufacturer any request from the MHRA to provide such samples or access, and communicate to the MHRA whether the manufacturer intends to comply with that request;

(f) cooperate with the MHRA on any preventive or corrective action taken to eliminate or mitigate the risks posed by devices;

(g) immediately inform the manufacturer about complaints and reports from healthcare professionals, patients and users about suspected incidents related to a device for which they have been appointed;

(h) register the manufacturer's devices with the MHRA's DORS database when instructed by the manufacturer.

if the manufacturer acts contrary to its obligations under these Regulations:

(a) terminate the legal relationship with the manufacturer; and

(b) inform the MHRA and, if applicable, the relevant notified body of that termination;

Why confinis?

We appreciate that manufacturers have a choice, but with an experienced and knowledgeable team we are confident that confinis can provide an independent, expert and effective service. Whereas distributors are also able to register manufacturers with the MHRA, they often will not have the necessary expertise and focus to provide the service required. confinis has an international team of advisers, skilled in solving problems in a challenging regulatory environment.

New regulations governing registration of medical devices and IVDs were implemented by the UK Government on January 1, 2021.

Date of Registration	Medical Devices	IVD
1 January 2021	New medical devices	New IVDs*
1 May 2021	Class III and Class IIb implantables; all active implantable medical devices	Annex II, List A
1 September 2021	Other Class IIb and all Class IIa devices	IVD List B, self-test IVDs
1 January 2022	Class I devices	General IVDs
1 July 2023	To place a device on the market in Great Britain, manufacturers will need to meet the requirements for placing a UKCA mark on their device	

*Devices/IVDs being placed on the UK market for the first time

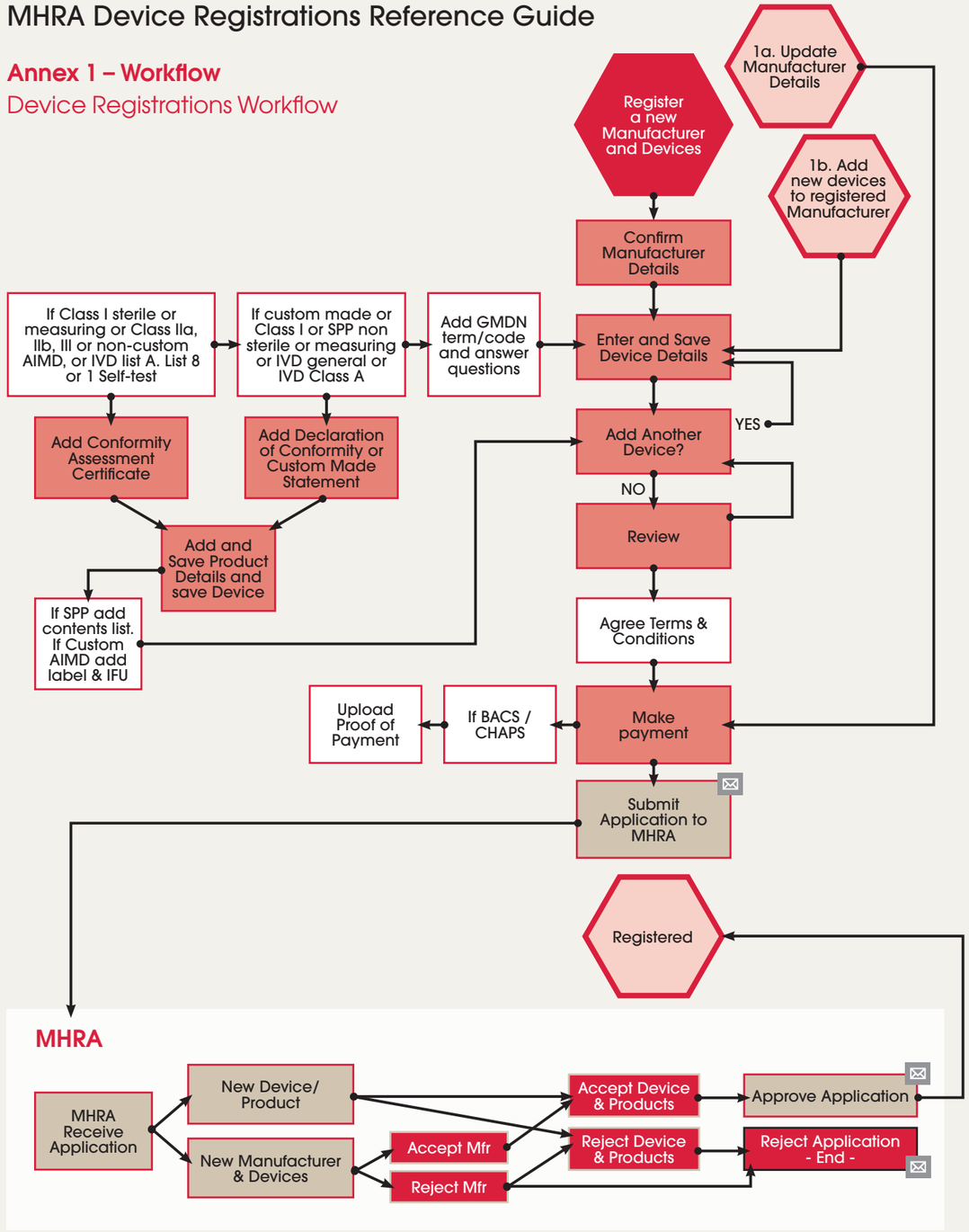
The Process

When an overseas manufacturer wishes to place a medical device or IVD on the UK market, confinis is ready to assist. Once a contract with confinis is concluded for UKRP services, the initial requirement will be for the manufacturer to supply a range of documents for review. This will include the list of devices and technical file(s). confinis will then conduct a high-level check of the technical file to confirm compliance with UKCA and a review of the necessary GMDN codes to determine insurance requirements. confinis can then proceed with registration.

MHRA Device Registrations Reference Guide

Annex 1 – Workflow

Device Registrations Workflow



Derived from Device Registrations Workflow, MHRA Reference Guide, September 2021.

Please contact us if you require further information about our UK Responsible Person service, UKCA marking, or assistance with any other regulatory matter. We're here to help!

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