

- ✓ DERKA has received offer of designation as a UK Approved Body for medical devices.
- ✓ Our end-point is a scope to match the combined scope of our two EU notified bodies #0124 and #0344.
- ✓ We have opted for a limited entry scope.
- ✓ By staggering our scope, we can start to deliver service as soon as possible.

### **Current scope:**

Non-active devices for anaesthesia, emergency and intensive care

Non-active devices for injection, infusion, transfusion and dialysis

Non-active ophthalmologic devices

*Non-active instruments*

Non-active medical devices for disinfecting, cleaning, rinsing

Non-active devices for in vitro fertilisation (IVF) and assisted reproductive technologies (ART)

Non-active cardiovascular implants

Non-active orthopaedic implants

Non-active functional implants

Non-active soft tissue implants

Bandages and wound dressings

Other medical devices for wound care

Non-active dental equipment and instruments

Dental implants

#### **DEKRA Customers**

Apply via your usual DEKRA contact. Your DEKRA contact will be able to provide all the information and support that you need.

#### **Non-DEKRA customers**

Apply to [certification.uk@dekra.com](mailto:certification.uk@dekra.com)

# Target scope extension

(target date Q2 2023)

IVD full scope

Active implantable medical devices for stimulation / inhibition

Non-active medical devices with measuring function

Non-active medical devices with measuring function

Suture material and clamps

Dental materials

Devices for extra-corporal circulation, infusion and haemopheresis

Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia

Devices for stimulation or inhibition

Active surgical devices

Active ophthalmologic devices

Active dental devices

Active devices for disinfection and sterilisation

Active rehabilitation devices and active prostheses

Active devices for patient positioning and transport

Active devices for in vitro fertilisation (IVF) and assisted reproductive technologies (ART)

Software

Parts incorporated within Medical gas supply systems

Imaging devices utilising ionizing radiation

Imaging devices utilising non-ionizing radiation

Monitoring devices of non-vital physiological parameters

Monitoring devices of vital physiological parameters

Devices utilising ionizing radiation

Devices utilising non-ionizing radiation

Devices for hyperthermia / hypothermia

Devices for (extracorporal) shock-wave therapy (lithotripsy)