

# UK RESPONSIBLE PERSON (UKRP)



## Choose Thema as your UKRP

We will be your point of reference in the UK market, ensure compliance with all UK regulatory requirements and independence from your Importer or Distributor.

**You can activate the service in 3 steps:**

### Step 1 >



#### Initial Fee

Review of your full Technical Documentation (TD) & Quality System (QS) documentation in collaboration with our **UK qualified partner agency**.

- The TD has to be provided in **English language**;
- we can ask you to **modify, revise and integrate your documentation**;
- involves a **fixed one-time cost + an hourly fee**.

### Step 2 >



#### UK Responsible Person Appointment

- This entails the signature of a **Quality Technical Agreement**;
- **fixed fee**.

### Step 3 >



#### Post-Market Activities

- **Registration** in MHRA database;
- **post-market surveillance and vigilance** activities;
- **handling communications** with MHRA;
- **UKCA marking support**.

Step 3 activities are managed through hourly fees: **you only pay for the hours you use**.