

UNITED KINGDOM Regulatory

DTx products in the United Kingdom are regulated as medical devices and must therefore be CE marked. Subsequently, products are subject to reviews by NHS and NICE for economic evaluation, reimbursement, and patient access.

Category Name	Medical Device
Conformity Assessment	CE Mark granted by a designated Authorized Notified Body CE Mark granted by a UK-designated Approved Body
Responsible Regulatory Agency	Medicines and Healthcare products Regulatory Agency (MHRA)
Products that Qualify For Regulatory Review	DTx manufacturers complete a self-assessment risk classification (MDCG) to determine which level of CE Mark is necessary. Class I products do not qualify for regulatory review. Some DTx products that were initially certified as Class I MDD , remain Class I under MDR . <i>Products that qualify for regulatory review include:</i> <ul style="list-style-type: none"> • Class IIa: Most DTx software falls under this classification, with some exceptions. • Class IIb: Includes DTx products with higher risks or consequences. • Class III: No Class III DTx products currently exist, but this is possible in the future.
Pre-Submission Opportunities	No process exists.
Guidelines To Be Met	UKCA Mark requirements (to be updated soon) are still derived from the EU CE Mark regulations. Key systems: <ul style="list-style-type: none"> • Company-wide quality management system (QMS) according to MDR article 10, compliant with ISO 13485 and product-specific technical documentation (MDR annex II and III, covering IEC 62304, IEC 62366, and ISO 14971). • Clinical evaluation report according to MDR Article 61 (annex XIV and XV), MDCG, and MEDDEV 2.7. • Post-market surveillance report according to MDR Article 85 for Class I and Article 86 for Class IIa, IIb, and III. Full regulation: MDR 2017/745
Other Guidelines	Future divergences from the EU MDR requirements to obtain the UKCA Mark are expected in the future.
Product Recognition	CE Mark (until July 2023) UKCA Mark (since January 2021)
Approximate Timing For Process Completion	For CE mark: 12–18 months, although the timeline is currently extended due to the limited number of notified bodies. Awaiting further guidance for DTx products regarding the UKCA process.
Cost	For CE mark: Cost is dependent on internal regulatory expertise and capacity. Total cost: ~ 60.000-100.000 EUR (including notified body and external consultants). Awaiting further guidance for DTx products regarding UKCA process.

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Reimbursement

Prescription Required?	Prescriptions are not required for products in the NHS App Library, since they have been deemed safe by the NHS.
Public Insurance Coverage	<p>This is the main pathway for product reimbursement, covering the entire population. Currently there are no dedicated pathways to receiving reimbursement on a national level. Local NHS organisations play a dominant role in funding and reimbursing DTx products. Key decision bodies for local DTx funding are the 43 Integrated Care Systems (ICSs), replacing the current 203 local Clinical Commissioning Groups (CCGs) in April 2022.</p> <p>The national NHS App Library includes DTx and other digital health products that fulfill the necessary criteria in the DTAC framework. Library inclusion does not provide reimbursement. Several initiatives exist for digital health solutions; however, neither is directly linked to national reimbursement:</p> <ul style="list-style-type: none"> • The National Institute for Health and Care Excellence (NICE, UK's HTA body) has published a framework for the assessment and evaluation of digital health technologies. • Several NHS Innovation Accelerator programs exist that can provide access to pilots with NHS organisations to build references.
Private Health Insurance	Private insurance represents a smaller segment, accounting for 10% of total healthcare expenditures. Reimbursement agreements with private health insurers have not experienced strong uptake, although some products are partially covered.
Employer-Sponsored Healthcare	Not common, but may become more relevant in the future.
Consumer-Funded	<p>Low willingness for consumers to pay out-of-pocket.</p> <p>Although the NHS App Library was designed to promote direct to consumer uptake, outcomes have been mixed.</p>