Target product profile template for DHTs

What is it and why is it important?

A **Target product profile (TPP) is a vital planning tool introduced by the FDA to streamline the "drug development process"**. A TPP serves as a strategic roadmap aligning stakeholders by providing a comprehensive vision for the final product and ensuring unified efforts toward a clear goal.

Key sections of the TPP

Attribute	Minimum acceptable result	Ideal result
Indications/use	Monitor [specific health metric] or facilitate [specific service].	Real-time, multi-functional health monitoring or services.
Target population	Adults with [specific condition] in urban settings.	Broad population across all demographics globally.
Efficacy	Accuracy of 80% for key health metrics.	Accuracy of >95% with predictive capabilities.
Safety	Meets all basic digital safety and data privacy standards (e.g. GDPR, HIPAA).	Fully encrypted, AI-driven data protection, certified by multiple international bodies.
Platform compatibility	Integration with major OS platforms (e.g. iOS, Android).	Universally compatible across devices and platforms.
Usability	User-friendly interface with limited onboarding required.	Intuitive design with zero learning curve and multilingual support.
Regulatory pathway	Authorized by FDA as Class I or Class II medical device.	Authorized by FDA, EMA, and other global authorities.
Manufacturing	Cloud-based platform with minimal server downtime.	Scalable, edge-computing infrastructure with 99.99% uptime.
Cost-effectiveness	Pricing is comparable to similar technologies.	Cost-effective with demonstrated return on investment (ROI) for healthcare providers.
Interoperability	Basic integration with electronic health records (EHRs).	Seamless, bidirectional data exchange with all major EHR systems.
Support	Limited online documentation and email support.	24/7 multi-channel support with real-time issue resolution.
Outcome monitoring	Periodic manual review of	Continuous, AI-based

	system metrics.	performance monitoring with automated alerts.

Adapted from: