



White LED

Ready to be used.

Blue LED

In delayed start mode.

Green LED

Shelf life calculation is ongoing. Product is valid.

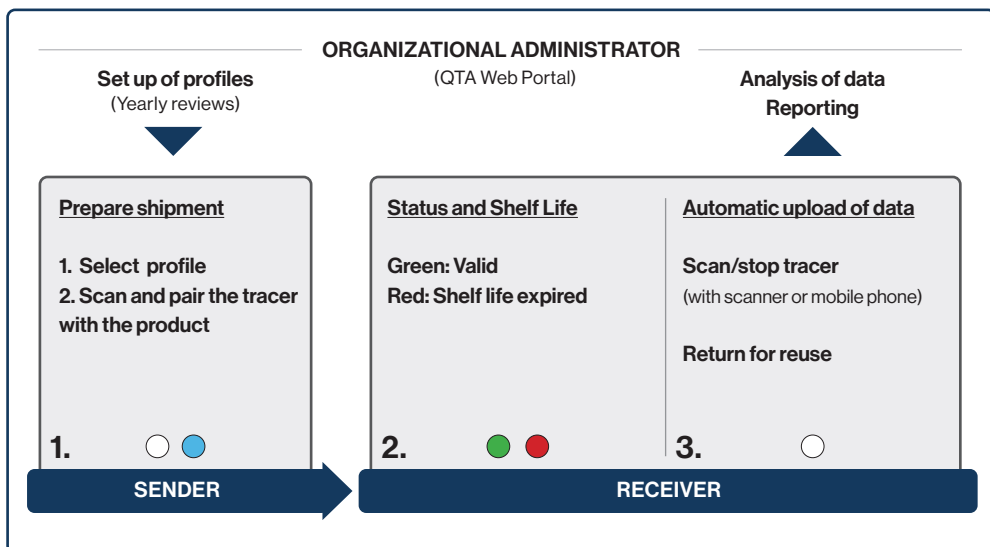
Red LED

Shelf life expired. Product is invalid.

QTA TRACER SYSTEM®

QUALITY – TRACEABILITY – ACCESSIBILITY

QTA Tracer System® workflow – As easy as 1-2-3



Specification

Medical device traceability	QTA Tracer (MDD Class IIa) Unique ID number
Measurement interval	Every minute, user configurable sample rate
Measurement accuracy	±0.1°C (Maximum) -20°C to +50°C ±0.15°C (Maximum) - 40°C to +70°
MKT	MKT calculation (Mean Kinetic Temperature)
Measurement resolution	0.0078 °c
Measurement range	Operating temperature -40°C to +70°C
Temperature sensor	Digital
Light sensor	Measure from 0.01 lux up to 83k lux
Accelerometer	Motion detection
Data storage	220 000 data points
Battery life	3 years, factory replaceable, not rechargeable
Battery type	Coin cell
Calibration	Standard calibration certificate NIST or optional ISO17025, 1-5 points calibration
Communication	Bluetooth 5, NFC tag with Bluetooth ID, Mobile/and or PC application
Shelf life delay	User configurable delay based on time or temperature - all data events are stored from log start.
Case Dimension Weight IP class	ABS Plastic material 14 mm x 52 mm x 57 mm 30 g IP67 (water resistance)
Device components	Recyclable Plastic (Medical, Biocompatibility ISO10993, US Pharmacopeia Class VI approved) Rubber Electronics
Packaging material	Corrugated cardboard
Certifications and conformity	CE Medical Device MDD Class IIa FCC (CFR Title 47, Part 15, subpart B Class B) RED RTCA/DO160G Section 21 IP67
Standards and guidelines	ISO9001:2015 ISO13485:2016 ISO14971:2020 GAMP5 ISBT 128 RoHS WEEE
Certification	ISO13485:2016, Medical Device Directive class IIa. ISO9001:2015
Validation of scanned data	Preconfigured for transfusion products according to ISBT 128 or any other standard to be configured
QTA Tracer System®	QTA Tracer System® creates, stores and manages individual profiles for the QTA Tracer. This allows a safe and quick profile selection. The QTA Tracer System® enables data export in pdf, csv or Excel formats. All configuration is done in the Tridentify QTA Web Portal.

Safeguarding as a Service®