TRIDENTIFY
SAFEGUARDING MEDICINES FOR LIFE

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SCIAMED

MONITORING COLD CHAIN INTEGRITY AND REAL-TIME SHELF-LIFE CALCULATION

Real-time shelf-life control system

The Safeguarding Shelf-Life Control System evaluates temperature and environmental data across the product lifecycle to calculate remaining shelf-life.

- Custom Programming: Tailored to the exact specifications of each product for personalised monitoring.
- Minimised Waste: Displays the remaining time for safe use, reducing unnecessary disposal.
- Real-Time Communication: Continuously provides updates on product durability.

Certified MedTech device

The QTA Tracer is classified as an MDD Class IIa MedTech device, meeting strict international standards for medical safety and quality.

- Global Compliance: Adheres to deviation reporting and regulatory requirements for local and international use.

For more information contact
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Safeguarding as a service

The QTA Tracer is an advanced, multi-use Bluetooth device designed for precise monitoring of cold chain environments. Its flexibility and reliability make it ideal for sectors such as biopharma, healthcare, and logistics, ensuring safe handling and transportation of sensitive products.

Advanced features for reliable monitoring

- Bluetooth 5 Connectivity: Enables wireless data transfer for easy and seamless communication.
- Long-Term Logging: Operates continuously without requiring frequent downloads, suitable for demanding environments.
- Event-Driven Logging: Monitors key parameters including:

- Temperature (with an accuracy of ±0.1°C
- Light (to safeguard light-sensitive products)
- Motion (to detect product handling or transport conditions).

These features provide a comprehensive and detailed view of the product's condition throughout the supply chain.

Precision and durability for demanding environments

- High Precision: Temperature measurements with market-leading accuracy of ±0.1°C.
- Rugged Design: IP67 classification ensures dust and water resistance, guaranteeing performance even in harsh conditions.

User friendly design

- Visual Status Feedback: Equipped with a clear RGB LED for instant, easy-to-understand updates.
- Offline Functionality: Operates independently of connectivity, ensuring reliability at all times.
- Easy Integration: Can be started and monitored via mobile devices or PC applications, allowing seamless adoption into existing workflows.

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Reusable and efficient

With its advanced technical features and reusable design, the QTA Tracer enhances operational efficiency while protecting sensitive products. It ensures patient safety across critical environments, making it an optimal choice for temperature monitoring in biopharma, healthcare, and logistics.

Category	Details
Medical Device	QTA Tracer (MDD Class IIa)
Traceability	Unique ID number
Measurement Interval	Every minute (user configurable sample rate)
Measurement Accuracy	±0.1°C (Max) -20°C to +50°C; ±0.15°C (Max) -40°C to +70°C
Measurement Resolution	0.0078°C
Measurement Range	-40°C to +70°C
Temperature Sensor	Digital
Light Sensor	Measures from 0.01 lux up to 83,000 lux
Accelerometer	Motion detection
Data Storage	220,000 data points
Battery Life	3 years (factory replaceable, not rechargeable)
Battery Type	Coin cell
Standard Calibration	NIST
Optional Calibration	ISO17025 (1-5 points calibration)
Calibration Certificate	Available as Standard or Option
Communication	Bluetooth 5, NFC tag with Bluetooth ID
User Applications	Mobile and/or PC application
Shelf-Life Calculation Delay	User configurable based on time or temperature - all events stored from log start.
Material	ABS plastic (ISO10993, US Pharmacopeia Class VI approved)
Dimensions	14 mm x 52 mm x 57 mm
Weight	30 g
IP Class	IP67 (water resistance)
Packaging Material	Corrugated cardboard
Conformity	CE, FCC, RoHS, WEEE
Standards and Guidelines	GAMP5, ISBT 128, ISO14971:2020
Certifications	ISO9001:2015, ISO13485:2016, Medical Device Directive Class IIa
Preconfigured Profiles	Designed for transfusion products (ISBT 128 or customisable standards)
System Capabilities	Create, store, and manage individual profiles for QTA Tracer
Data Export	Available in PDF, CSV, or Excel formats
Configuration	Managed via Tridentify QTA Web Portal

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