

## Enhancing Traceability and Counterfeit Detection for Roche Diabetes Care India Private Limited.

Optimising medical device traceability and authentication at Roche Diabetes Care India with GS1 Standards.



### Challenge

Roche Diabetes Care encountered pressing challenges in ensuring the authentication of their products and mitigating counterfeit activities. Key issues included:



#### Lack of Product Authentication:

Ensuring that their products, including those for future exports, could be reliably identified as authentic by stakeholders in the supply chain and end-consumers.



#### Inefficient Counterfeit Management:

Struggling to track and manage counterfeit incidents effectively, including for products shipped to international markets.



#### Challenges in Meeting Regulatory Compliance:

Roche Diabetes Care needed to adhere to 'CE' compliance requirements, which mandated serialization of every product unit. However,

serialization alone was not sufficient; a robust mechanism to track and authenticate serialized products was essential.



#### Market Risks & Weakening Consumer Trust:

Counterfeit products not only jeopardized Roche Diabetes Care's brand reputation but also posed risks to consumer safety and satisfaction, leading to an urgent need for preventive measures.



#### Initiating Timely Recall:

Communicating the user in case of any product recall is an important aspect towards true patient care.

## SOLUTION

To address these challenges, GS1 India implemented an advanced serialization and traceability solution for Roche Diabetes Care. By leveraging GS1 standards, including GS1 DataMatrix (2D barcodes) and the Smart Consumer Mobile App, Roche Diabetes Care successfully established a system capable of both enhancing traceability and mitigating counterfeit risks.

### Key features and solutions included:

- 1. Serialization Mechanism:** Each medical device was assigned a unique serial number along with GTIN, manufacturing details, batch number using GS1 DataMatrix (2D barcodes), ensuring complete identification and traceability.
- 2. Counterfeit Detection:** GS1 India deployed a 'Suspect Activity Notification Mechanism', providing Roche Diabetes Care with email alerts in the following scenarios:
  - **Multiple Scans of a Single Pack:** If a product pack is scanned over a specified count via the Smart Consumer Mobile App, an email alert is triggered to Roche Diabetes Care's admin team for investigation.
  - **Scans from Different Locations:** Alerts are triggered when the same serialised product is scanned within specified range (miles/kilometres) and/or in multiple countries, flagging potential fraudulent activities.
  - **Batch ID Manipulation:** If a scanned product displays mismatched batch details or invalid expiry dates, Roche Diabetes Care is notified of possible tampering or manipulation of serialised product.
  - **Geography-Based Reports:** Each scan captured location data, enabling Roche Diabetes Care to monitor the product's geographical movements and track any anomalies.
- 3. Product Recall Notifications:** In the event of a product recall, Roche could upload the affected batch details into a predefined template. Consumers using the Smart Consumer Mobile App were notified during product scans, allowing them to seek assistance and ensuring Roche Diabetes Care complied with regulatory recall processes.
- 4. Integrated Traceability System:** DataKart, DataKart Trace and Smart Consumer Mobile App were integrated into Roche Diabetes care's processes, enabling seamless creation of accurate labels and real-time data management. This ensured streamlined operations and reduced manual errors.

## BENEFITS

The implementation of GS1 India's solutions brought transformational benefits to Roche Diabetes Care, enhancing operational efficiency, traceability, and consumer trust. The key benefits achieved were:

- 1. Enhanced Product Integrity:** Serializing products and integrating GS1 standards ensured that all units were traceable and authenticated, safeguarding Roche Diabetes Care's brand credibility.
- 2. Proactive Incident Management:** Email alerts for suspect activities empowered Roche Diabetes Care to take swift and preventive actions against counterfeit incidents, protecting both consumers and the company.
- 3. Improved Consumer Engagement:** The Smart Consumer Mobile App enabled end users to verify product authenticity effortlessly, strengthening trust and satisfaction.
- 4. Regulatory Compliance:** The solutions ensured adherence to 'CE' compliance regulations, supporting Roche Diabetes Care's export operations seamlessly.
- 3. Operational Efficiency:** DataKart facilitated efficient serialization along with GTIN management, batch management, and label generation (GS1 DataMatrix), optimizing supply chain processes.
- 4. Strengthened Brand Reputation:** By implementing robust counterfeit detection and traceability measures, Roche Diabetes Care reinforced its reputation as a trusted healthcare provider in global markets.

## Testimonial from Roche Diabetes Care India Private Ltd



“At Roche Diabetes Care, we understand the importance of product integrity and traceability in healthcare. With GS1 India, we have integrated DataKart and DataKart Trace into our processes, allowing us to generate accurate labels and monitor potential suspect activities in real time. By leveraging GS1 DataMatrix (2D barcodes) and the Smart Consumer Mobile App, we have empowered our customers to authenticate products seamlessly, enhancing safety and transparency.

Beyond traceability, GS1 India's Product Master Management system has streamlined our GTIN creation and serialization, ensuring accuracy and efficiency across our supply chain. Our partnership with GS1 India is a testament to the power of global standards in building trust, driving efficiency, and delivering excellence in healthcare.”

**Rishubh Gupta, General Manager - India & Neighbouring Markets**



**ACCU-CHEK, ACCU-CHEK ACTIVE, ACCU-CHEK INSTANT and mySugr are trademarks of Roche. © 2025 Roche Diabetes Care. All rights reserved.**



**Get started with next generation barcodes!**

Unlocking new possibilities for better world.

[www.gs1india.org/content/contact-us](http://www.gs1india.org/content/contact-us)

### GS1 INDIA

BG00, Ground Floor, Tower-B, World Trade Centre, Nauroji Nagar, New Delhi - 110029

T +91 (11) 4289 0890 | E [info@gs1india.org](mailto:info@gs1india.org)

[www.gs1india.org](http://www.gs1india.org)