December 13, 2021

Dockets Management Staff (HFA–305)
Food and Drug Administration,
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: **Initial Comments** of AIM North America on:
Docket No. FDA-2027-D-6841
Select Updates for Unique Device Identification: Policy Regarding Global Unique Device Identification Database Requirements for Certain Devices
Federal Register, Volume 86, Number 196, pages 57154 - 57156

To Whom It May Concern:

We are pleased to submit the enclosed comments regarding the above referenced docket and regulatory information number which appeared in Federal Register, Volume 86, Number 196, pages 57154 - 57156.

These comments were prepared by members of the AIM North America UDI Work Group, all of whom are subject matter experts of the design and application on automatic identification technology. Founded in 1970, AIM is an industry trade association that represents the providers and users of technologies, systems, and services that capture, manage, and integrate accurate data into larger information systems that improve processes enterprise-wide. AIM North America is a chapter of AIM, Inc. In this role we advocate, educate, and coordinate with other subject matters experts including the FDA, GS1, MHI, AHRMM, RPA, AIAG to further the adoption of AIDC usage in industry.

AIM serves as the secretariat for the U.S. Technical Advisory Group (TAG) ISO/IEC JTC 1/SC 31 | Automatic Identification and Data Capture Techniques. This group formulates the U.S. position on all work related to the standardization of data formats, syntaxes, structures, and encoding, along with capture technologies for automatic identification and data capture and their associated devices utilized in inter-industry applications and international business interchange.

AIM North America appreciates this opportunity to submit comments in response to the Food and Drug Administration's (FDA) Notice in the above-captioned docket, seeking comment on the agency's approach to Select Updates for Unique Device Identification: Policy Regarding Global Unique Device Identification Database Requirements for Certain Devices.

As subject matter experts in asset tracking technologies including Barcodes (1D & 2D Symbols), Radio Frequency Identification (RFID), Real Time Location System (RTLS), Internet of Things (IoT), and other technologies. AIM North America will be happy to respond to any technical support requests from the FDA about the value of standards or the implementation of the rule.

Sincerely yours,

Jeanne Duckett
AIM North America Board Chair

Patti Blessing
AIM Board Member
AIM North America UDI Work Group Chairperson

100 Allegheny Drive, Suite 105C
Warrendale, PA 15086 USA

Phone: +1 724 742 4473
email: info@aim-na.org

www.aim-na.org

INTRODUCTION AND SUMMARY

AIM North America UDI Work Group, as an industry recognized advocate for standards development and advocacy of AIDC technologies appreciates this opportunity to submit comments in response to the Food and Drug Administration's (FDA) Comments Notice for Select Updates for Unique Device Identification: Policy Regarding Global Unique Device Identification Database Requirements for Certain Devices; Docket No. FDA-2027-D-6841. The AIM NA UDI Work Group recently published a paper to assist organizations in understanding how AIDC technologies and standards are being used to ensure traceability for all lines of devices.

The following comments echo those submitted by the Association for Health Care Resource & Materials Management (AHRMM), Learning UDI Community (LUC); a collaboration of stakeholders from across the health care field including providers, manufacturers, distributors, software application providers, standards organizations, the FDA, and other interested participants

COMMENTS

We recommend that information related to all Class I Medical Devices be included in the GUDID without exception. The intent of the GUDID is to provide a single repository of data for all regulated medical devices. This source in turn would allow patients, consumers, retailers, health care providers and any interested stakeholder the ability to verify legitimacy and confirm a specific product is an FDA regulated medical device. Categorizing Class I Medical Devices that are sold direct-to-consumer through brick and mortar and on-line stores as "consumer health products" and exempting them from inclusion in the GUDID will cause confusion and potentially increase consumer risk. The rationale for this recommendation is outlined below.

- The UDI is intended to support a host of patient/user-centric activities (e.g., recalls, adverse event reporting, eIFUs). Likewise, the GUDID is intended to serve as a comprehensive database of all regulated medical devices. If a product is risky enough to be regulated by the FDA, it should be trackable in a public database. There is no reason to exclude consumer health products from the broader ecosystem that is developing.

- Advocacy efforts are underway to improve the medical device recall process to make it more transparent and timelier for all stakeholders. One way to improve the process is ensuring the UDI-DI is included in all recall information. Excluding information from GUDID could negatively impact consumers purchasing those Class 1 Medical Devices classified as consumer health products.

- Experience during the COVID pandemic has highlighted the risks associated with counterfeit and sub-standard PPE. Many of these products such as masks, gloves, and gowns, are considered Class I medical devices and are distributed through multiple channels including as healthcare consumer products. Due to shortages, health care providers have been forced to purchase these products from brick and mortar and on-line retail stores.

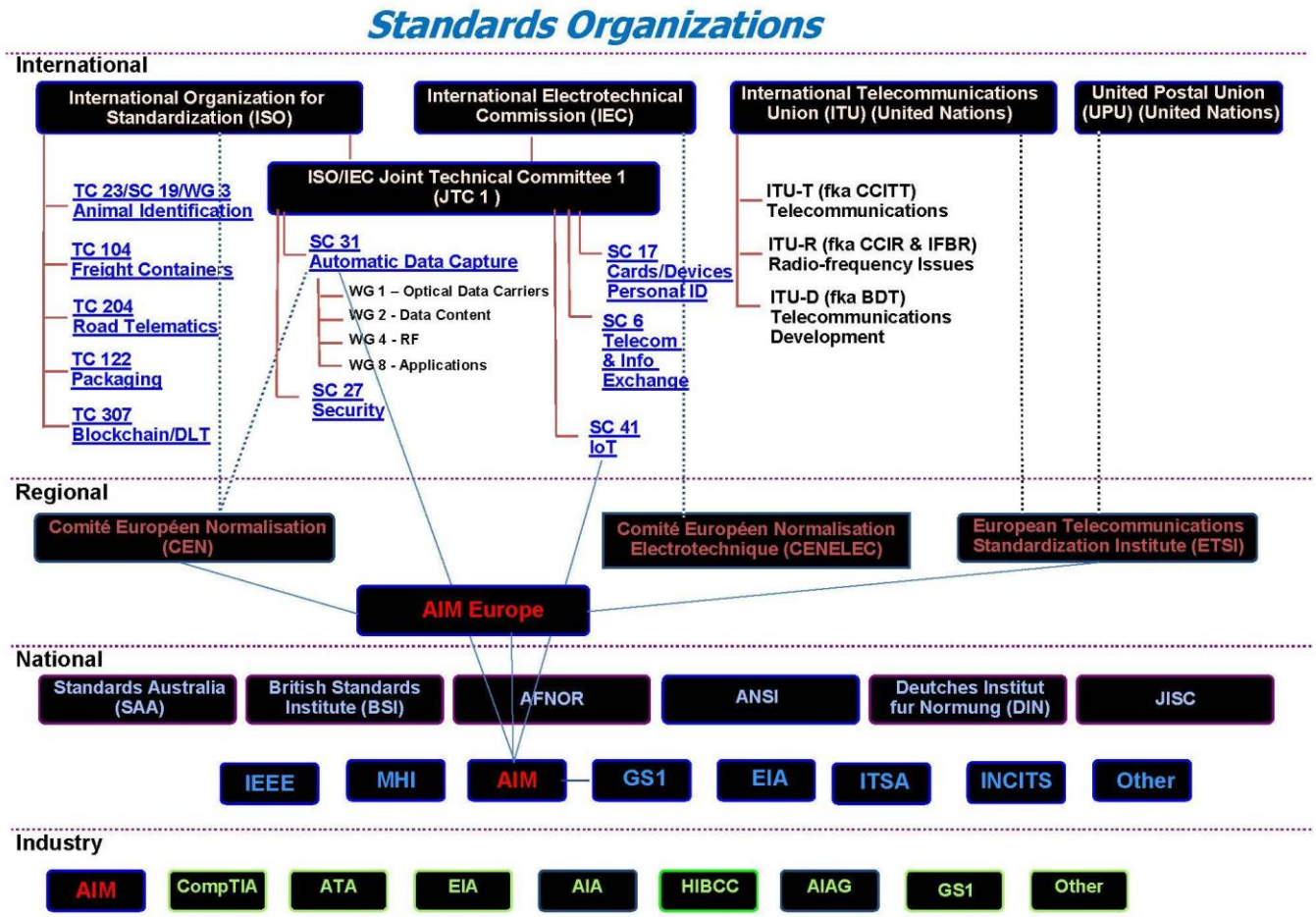
- The guidance indicates that the policy does not apply to Class I Medical Devices sold to "Professional Healthcare facilities". Information related to these devices must be included in GUDID. The clarification that devices sold to both brick and mortar and on-line retail stores as well as professional healthcare facilities must be included in GUDID is included in a footnote. There is concern that manufacturers of Class I products will interpret this guidance to mean that if any of their products are sold in brick and mortar or on-line stores that category of product is exempt from inclusion in the GUDID. A policy that requires inclusion of data from all Class I products in GUDID eliminates confusion.

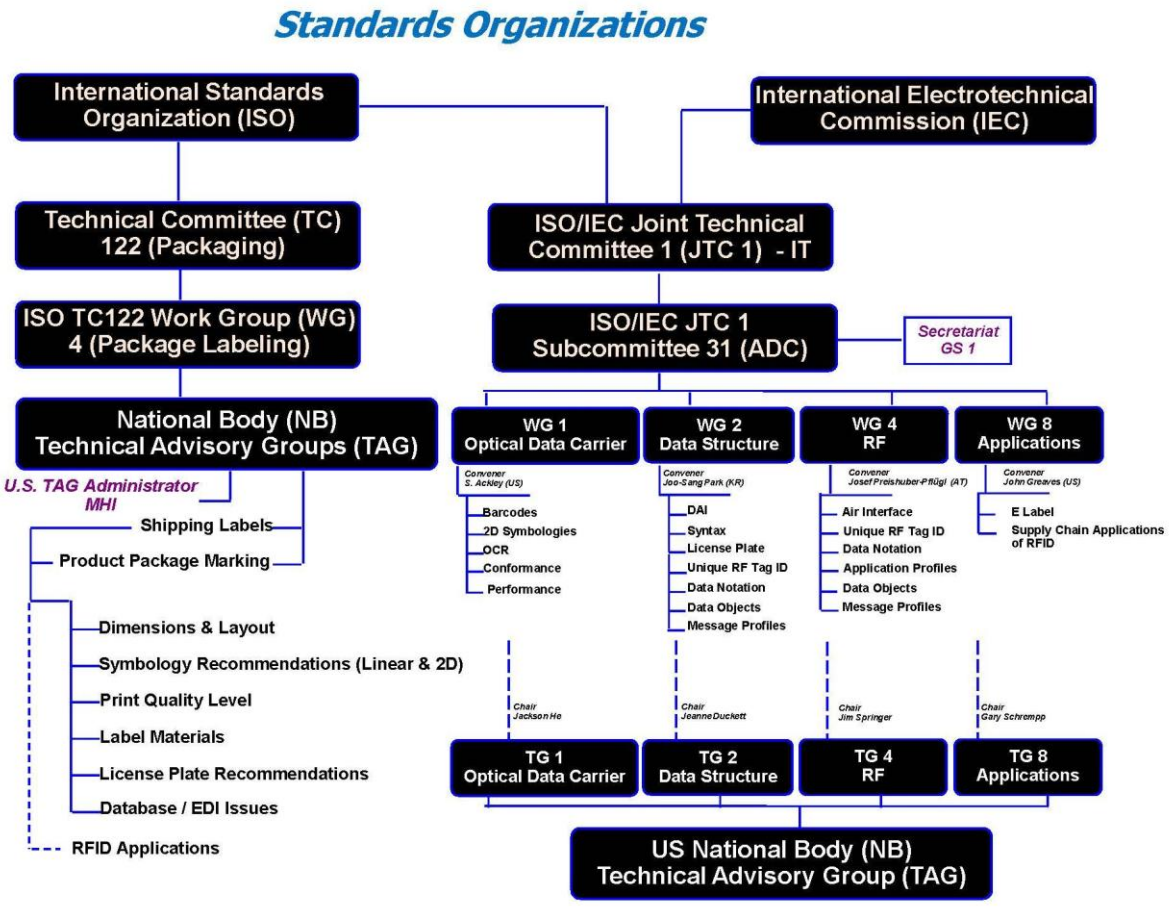
- Care continues to move from formal health care settings into patient's homes. Brick and mortar and on-line retail stores exist to serve this growing home health patient population. It is unclear if Class I medical devices sold in this setting would be included in the GUDID.

- The category of Class I devices includes a large, diverse group of products produced by a wide range of manufacturers with varying levels of expertise and internal controls. Because these devices are largely 510k-exempt, the FDA does not have a means to monitor performance and safety. The implementation of UDI was specifically intended to help bring clarity to this segment of class I devices.

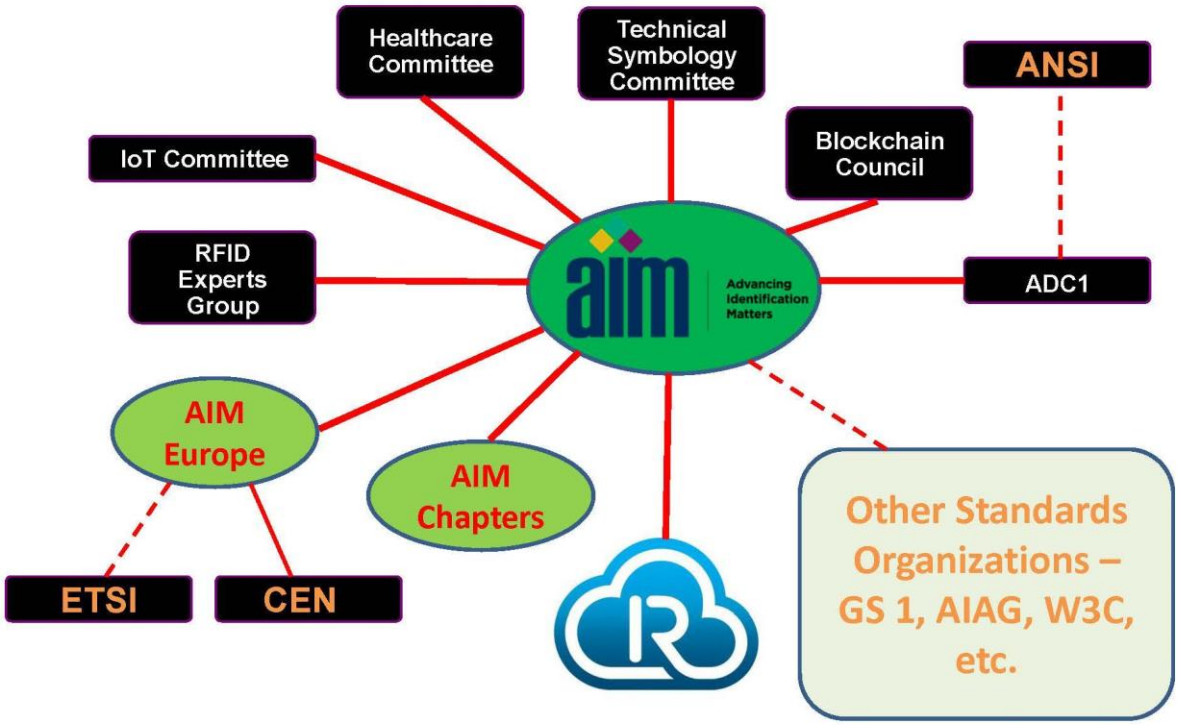
- We are unaware of any studies or data backing up the contention that UPNs for Class I medical devices (as opposed to general retail products) change significantly more often than the UDI-DI for other categories of medical devices.

APPENDIX A

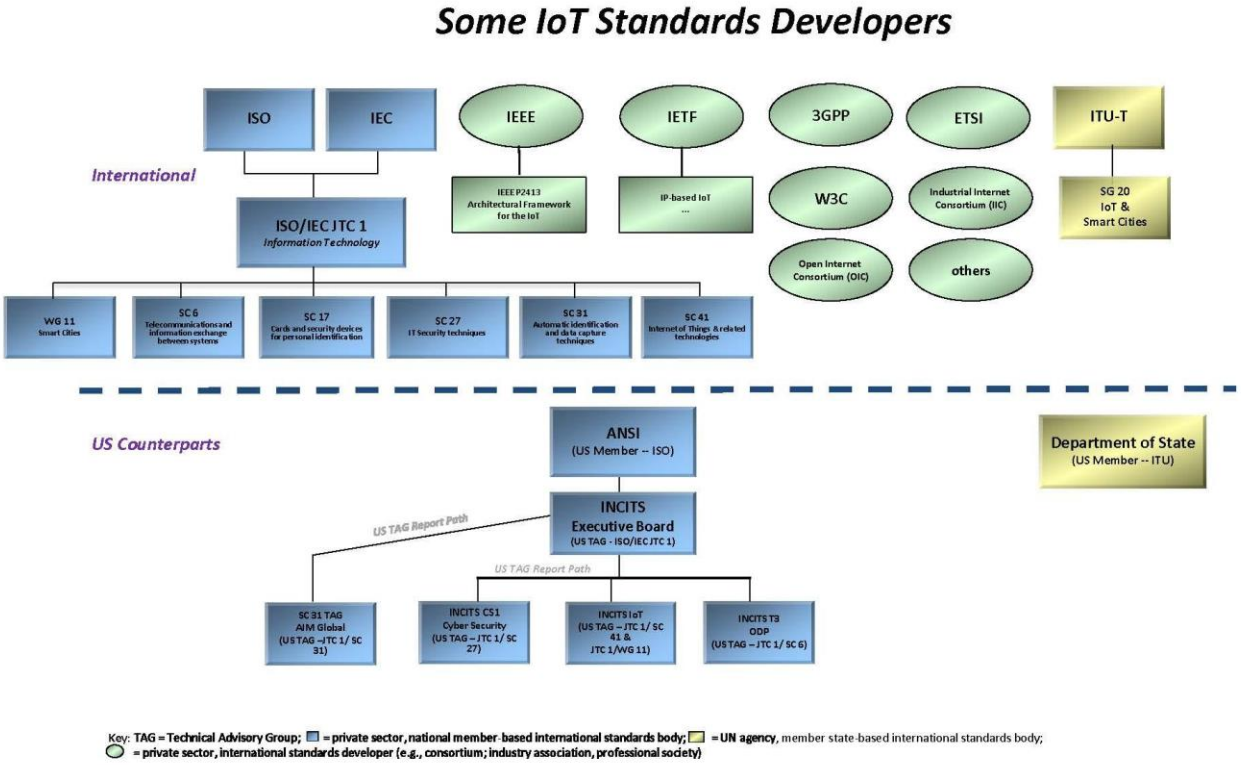

Standards Organizations
International
International Organization for Standardization (ISO)
International Electrotechnical Commission (IEC)
International Telecommunications Union (ITU) (United Nations)
United Postal Union (UPU) (United Nations)
TC 23/SC 19/WG 3 Animal Identification
TC 104 Freight Containers
TC 204 Road Telematics
TC 122 Packaging
TC 307 Blockchain/DLT
ISO/IEC Joint Technical Committee 1 (JTC 1)
SC 31 Automatic Data Capture
WG 1 – Optical Data Carriers
WG 2 - Data Content
WG 4 - RF
WG 8 - Applications
SC 27 Security
SC 17 Cards/Devices Personal ID
SC 6 Telecom & Info Exchange
SC 41 IoT
ITU-T (fka CCITT) Telecommunications
ITU-R (fka CCIR & IFBR) Radio-frequency Issues
ITU-D (fka BDT) Telecommunications Development
Regional
Comité Européen Normalisation (CEN)
Comité Européen Normalisation Electrotechnique (CENELEC)
European Telecommunications Standardization Institute (ETSI)
AIM Europe
National
Standards Australia (SAA)
British Standards Institute (BSI)
AFNOR
ANSI
Deutches Institut fur Normung (DIN)
JISC
IEEE
MHI
AIM
GS1
EIA
ITSA
INCITS
Other
Industry
AIM
CompTIA
ATA
EIA
AIA
HIBCC
AIAG
GS1
Other


Standards Organizations
International Standards Organization (ISO)
International Electrotechnical Commission (IEC)
Technical Committee (TC) 122 (Packaging)
ISO/IEC Joint Technical Committee 1 (JTC 1) - IT
ISO TC122 Work Group (WG) 4 (Package Labeling)
ISO/IEC JTC 1 Subcommittee 31 (ADC)
Secretariat GS 1
National Body (NB) Technical Advisory Groups (TAG)
WG 1 Optical Data Carrier
WG 2 Data Structure
WG 4 RF
WG 8 Applications
U.S. TAG Administrator MHI
Convener S. Ackley (US)
Barcodes
2D Symbologies
OCR
Conformance
Performance
Convener Joo-Sang Park (KR)
DAI
Syntax
License Plate
Unique RF Tag ID
Data Notation
Data Objects
Message Profiles
Convener Josef Preishuber-Pflügl (AT)
Air Interface
Unique RF Tag ID
Data Notation
Application Profiles
Data Objects
Message Profiles
Convener John Greaves (US)
E Label
Supply Chain Applications of RFID
Shipping Labels
Product Package Marking
Dimensions & Layout
Symbology Recommendations (Linear & 2D)
Print Quality Level
Label Materials
License Plate Recommendations
Database / EDI Issues
RFID Applications
Chair Jackson He
Chair Jeanne Duckett
Chair Jim Springer
Chair Gary Schrempp
TG 1 Optical Data Carrier
TG 2 Data Structure
TG 4 RF
TG 8 Applications
US National Body (NB) Technical Advisory Group (TAG)

AIM Relationships



Some Key IoT Standards Developers



APPENDIX B

AIM Ultracode International Symbology Standard

AIM 7351731 Medical Electrical Equipment & Sys Electro Immunity Test for RFID Readers

AIM ISS DotCode Symbology Specification

Global Numeric Code Issuing Agencies in accordance with ISO/IEC 15459.

ISO/IEC 15459-1:2014 Information Technology - Automatic Identification And Data Capture Techniques - Unique Identification - Part 1: Individual Transport Units

ISO/IEC 15459-2:2015 Information Technology — Automatic Identification and Data Capture Techniques — Unique Identification — Part 2: Registration Procedures

ISO/IEC 15459-3:2014 Information technology — Automatic Identification and Data Capture Techniques — Unique Identification — Part 3: Common Rules

ISO/IEC 15459-4:2014 Information Technology - Automatic Identification and Data Capture Techniques - Unique Identification - Part 4: Individual Products and Product Packages

ISO/IEC 15459-5:2014 Information technology — Automatic Identification and Data Capture Techniques — Unique Identification — Part 5: Individual Returnable Transport Items (RTIs)

ISO/IEC 15459-6:2014 Information technology — Automatic Identification and Data Capture Techniques — Unique Identification — Part 6: Groupings

ISO/IEC 15459-8:2009 Information Technology — Unique Identifiers — Part 8: Grouping of Transport Units

ISO/IEC 15961 - Information Technology - Data Protocol for Radio Frequency Identification (RFID) for Item Management

ISO/IEC 15961 – Data Constructs Register

GS1/ ISO Standards list

ISO Standard	GS1 Component
ISO/IEC 15459-6	GTIN (Global Trade Item Number
ISO/IEC 15459-4	SGTIN (Serialized Global Trade Item Number
ISO/IEC 6523	GLN (Global Location Number
ISO/IEC 15459-1	SSCC (Serial Shipping Container Code
ISO/IEC 15459-4 & 5	GIAI (Global Individual Asset Identifier
ISO/IEC 15459-5	GRAI (Global Returnable Asset Identifier
ISO/IEC 15418	GSRN (Global Service Relationship Number
ISO/IEC 15418	GDTI (Global Document Type Identifier

ISO/IEC 15418	GINC (Global Identification Number for Consignments
ISO/IEC 15459-6	GSIN (Global Shipment Identification Number
ISO/IEC 15418	GCN (Global Coupon Number
ISO/IEC 15418	CPID (Component / Part Identifier
ISO/IEC 15418	Application Identifiers
ISO 22274	Global Product Classification (GPC
IETF RFC 3986	EPC URI Syntax
ISO 9735	EANCOM syntax
UN/CEFACT UNSMs	EANCOM content
W3C XML	GS1 XML syntax
W3C XML	GS1 XML content
ISO/IEC 15424	Symbology identifiers
ISO/IEC 15420	EAN/UPC
ISO/IEC 16390	ITF-14
ISO/IEC 15417	GS1-128
ISO/IEC 24724	GS1 DataBar
ISO/IEC 16022	GS1 DataMatrix
ISO/IEC 24723	GS1 Composite
ISO/IEC 18004	GS1 QR Code
ISO/IEC 18000-63	UHF Class 1 Gen 2 /IEC 18000-63
ISO/IEC 18000-3	HF Class 1 Gen 2
ISO/IEC 15962	EPC Tag Data Standard
ISO/ICE 24791-5	Low-level Reader Protocol (LLRP)
ISO/IEC 24791-2	Application Level Events (ALE)
ISO/IEC 24791-3	Reader Management (RM)
ISO/IEC 24791-3	Discovery, Confguration, and Initialization (DCI)
ISO/IEC 19987	EPC Information Services
ISO/IEC 19988	GS1 Core Business Vocabulary (CBV)