Public Health Regulations

(sampling and performing Corona tests) (amendment), 2022

IVD Product Identification Code

Information Security Directive

Version: 1.0

Release Date: Aug. 08 2022

Approval Date	Author	Ver.	Update subject
08/08/2021	Alex Levin	1.0	Whole document, initial reduction

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Introduction

1.1. This Directive is intended to guide the target organizations and individuals regarding the implementation of the Public Health Regulations in its updated version, in field of diagnostic products identification coding, in order to obtain reliable test results in the process of performing remotely monitored tests.

2. Definitions

MOH	Ministry of Health of Israel
PHR	Public Health Regulations (sampling and performing Corona tests) (amendment), 2022
Manufacturer	(A) a person that holds an application approved by MOH or a license issued by the MOH for such product, or if such product is not the subject of an approved application or license, the person who manufactured the product. (B) a co-licensed partner of the person described in subparagraph (A) that obtains the product directly from a person described in this subparagraph or subparagraph (A) or (C); or (C) an affiliate of a person described in subparagraph (A) or (B) that receives the product directly from a person described in this subparagraph or subparagraph (A) or (B).
Dispenser	A retail pharmacy, hospital pharmacy, a group of chain pharmacies under common ownership and control that do not act as a wholesale distributor, or any other person authorized by law to dispense or administer prescription drugs, and the affiliated warehouses or distribution centers of such entities under common ownership and control that do not act as a wholesale distributor.
Repackager	A person who owns or operates an establishment that repacks and relabels a product or package for further sale or distribution without a further transaction.

Homogenous case	A sealed case containing only product that has a single product number belonging to a single lot.
Package	Smallest individual saleable unit of product for distribution by a manufacturer or repackager that is intended by the manufacturer for ultimate sale to the dispenser of such product.
IVD	In vitro diagnostic products are those reagents, instruments, and systems intended for use in diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease or its sequelae. Such products are intended for use in the collection, preparation, and examination of specimens taken from the human body.
Product	In meaning of IVD, Medical devices and accessories used to perform tests on samples, (e.g., blood, urine and tissue that has been taken from the human body) in order to: Help detect infection. Diagnose a medical condition. Prevent disease.
2D GS1 DataMatrix	GS1 Data Carrier (bar code symbology) solution that has two-dimensional (2D) matrix bar code, consisting of black and white “cells” or modules, that can be arranged in a square or rectangular matrix.
GTIN	A Global Trade Item Number (GTIN) is a unique and internationally recognized identifier for a product.
Unique Serial Number	A number indicating place in a series of production and used as a means of identification.
Unified Diagnostic Product Identifier	Standardized graphic that includes, in both human-readable form and on a machine-readable data carrier that conforms to the standards developed by a widely recognized international standards development organization, the standardized numerical identifier, lot number, serial number and expiration date of the product.

3. Background

3.1. The MOH has updated the Public Health Regulations (sampling and performing Corona tests) (amendment) in July 2022. The MOH outlines critical steps to build an electronic interoperable process that will be in place after 3 months of adaptation period. The process requires to identify certain diagnostic products as they are distributed within the State of Israel.

3.2. Section A of the Public Health Regulations (sampling and performing Corona tests) 2021, set forth new definitions to Covid-19 test. The new subsection C14(b) of the Public Health Regulations (sampling and performing Corona tests) sets forth new requirements related to diagnostic product identifiers (UDPI). The Unified Diagnostic Product Identifier MUST be adopted by healthcare providers to ensure the testing reliability based on unified product identifier by verification of every single test kit released by manufacturers, repackagers, wholesale distributors, and dispensers to facilitate the tracing of products through the pharmaceutical distribution supply chain. Failure to comply with the requirements of section C14(b) is a prohibited act under section A7(a) of the Public Health Regulations (sampling and performing Corona tests) and is subject to enforcement action under the Public Health Regulations (sampling and performing Corona tests) (amendment).

4. Scope of Directive

4.1. This directive is intended to help healthcare providers, manufacturers and repackagers understand and satisfy the requirements of subsection C14(b) of the Public Health Regulations (sampling and performing Corona tests) (amendment), respectively, to affix or imprint or engrave a product identifier to each diagnostic device, individual package and homogenous case of product that they intend to introduce in a transaction into commerce. The requirements in this directive are intended to assist manufacturers and repackagers in adoptinging standardized format for the human- and machine-readable information that is contained in the product identifier. The requirements set forth in this document do not change the MOH linear barcode requirements.

5. 2D Barcode Requirements

5.1. Manufacturers, repackers, relabelers, and private label distributors of drug products who are subject to the establishment registration and drug listing requirements in "Amar" law, are responsible for placing the appropriate 2D barcode on the product.

5.2. The UDPI MUST comply with ISO/IEC 15418:2016 Information Technology - Automatic Identification and Data Capture Techniques - Application Identifiers GS1 and Data Identifiers and Maintenance ASC MH10.

5.3. The UDPI structure MUST comply the GS1 General Specifications current version. The current version is available at the following link: https://www.gs1.org/docs/barcodes/GS1_General_Specifications.pdf

5.4. The UDPI machine readable representation must appear as GS1 Data Matrix Standard for healthcare Industry in accordance with the following rules: https://www.gs1.org/docs/gsmp/healthcare/GS1_Healthcare_GTIN_Allocation_Rules.pdf

5.4.1. The UDPI MUST contain the following Application Identifiers(AI):

5.4.2. AI(01) GTIN - 14-digit Global Trade Item Number - 14 numeric digits, predefined length.

5.4.3. AI(17) Expiration date – 6 numeric digits, predefined length.

5.4.4. AI(10) Batch/Lot – up to 20 characters. The Function 1 Symbol Character (FNC1) required, unless this element string is the last one encoded.

5.4.5. AI(21) Serial number - up to 20 characters. The Function 1 Symbol Character (FNC1) required, unless this element string is the last one encoded.

5.5. The UDPI GS1 2D Data Matrix MUST be affixed, or imprinted, or engraved on the same surface as the diagnostic element as shown in the following sample figure:

5.6. The digital version of the UDPI lable SHOULD be issued as a vector graphics file. Such format allows to enlarge the image with no contrast degradation. This measure will provide the best optic read readability on any display of mobile devices.

5.7. The human-readable UDPI repersentation MUST comply the GS1 Human Readable Interpretation (HRI) Implementation Guideline. The current version is available at the following link: https://www.gs1.org/docs/barcodes/HRI_Implementation_Guide.pdf

5.8. In addition the HRI MUST contain the textual conotation in its corelation to each (AI) field and MUST appear on every single package of the product, near tits machine-readable representation, as shown in the following sample figure:

GTIN(01) 05060478880004
PROD DATE 2017-11-13
SERIAL(21) OGA1645002
BATCH/LOT(10) B123CR890J

6. UDPI Scanned Value (Composition)

6.1. The UDPI MUST have the data structure schema as follows:

UDPI=([GTIN][EXP DATE][LOT]FNC1[SERIAL])

6.2. The FNC1 separator character is placed immediately after a non-predefined length element string (Lot/Batch) and is followed by the GS1 Application Identifier (21) of the next element string (Identifier).

6.3. The UDPI GS1 HRI Data Encoded, once scanned, MUST have the following textual HRI representation:

UPDI Example: 01725678901234517230320 10TLV3378 213456789012

6.4. The separator character appears in the decoded data string as control character <GS> (ASCII value 29, (decimal), 1D (hexadecimal)). A separator character SHOULD NOT be used at the end of the last element string encoded in a GS1 barcode.

Note: The FNC1 is not shown in human readable interpretation, but when scanned by consumer barcode applications, can be visually identified as a “space” symbol before (21) as shown above in 6.3.