

WHO/PQS/E003/BC01.1 Original: English Distribution: General

TITLE: Global asset identification

Specification reference:E003/BC01.1Product verification protocol:E003/BC01-VP.1Issue date:8 July 2019Date of last revision:New specification

Contents

1.	Scope	2			
2.	Terms and definitions	2			
3.	Normative references (use most current version)	2			
4.	Requirements				
4.	4.1 Symbology and required information	3			
	4.1.1 GS1-128 compliance	3			
	4.1.2 Required barcode information	3			
	4.1.3 Human readable information	3			
	4.1.4 Database connection	3			
4.	4.2 Performance	4			
	4.2.1 Code quality	4			
	4.2.2 Operational lifetime	4			
	4.2.3 Durability	4			
	4.2.4 Tag location	5			
	4.2.5 Application and activation				
	4.2.6 Adhesion (if used)				
	4.2.7 Non-adhesive connection (if used)				
4.	4.3 Verification	5			
5.	Packaging	5			
6.	On-site installation	6			
7.	Product dossier	6			
8.	On-site maintenance	6			
9.	Change notification6				
10.	Defect reporting	6			
Rev	Pavisian history 7				

1. Scope

Country cold chain managers and other stakeholders involved in cold chain equipment management require technologies to more effectively track and manage cold chain equipment information. Cold chain appliances often come with a serial number located on the appliance. However, on many cold chain products or devices it is often challenging to access the back of the equipment where the asset tag showing the serial number and other information is located. Additionally, the location on equipment and the format of information across manufacturers of WHO PQS prequalified appliances is inconsistent.

This specification sets out the requirements for asset tagging of products and devices. Testing and verification of some requirements in this specification is necessary and these activities must be carried out and confirmed by the legal manufacturer of the tagged product or device, or the producer of the asset tags themselves. There is no related verification protocol for this specification.

2. Terms and definitions

Asset tag: a label containing a unique barcode and other information attached to a cold chain appliance.

In writing: Communication by letter, fax or email.

<u>Legal manufacturer</u>: The natural or legal person with responsibility for the design, manufacture, packaging and labelling of a product or device before it is placed on the market under the person's own name, regardless of whether these operations are carried out by that person or on that person's behalf by a third party.

<u>Montreal Protocol:</u> The Montreal Protocol, finalized in 1987, is a global agreement to protect the stratospheric ozone layer by phasing out the production and consumption of ozone-depleting substances (ODS).

<u>Reseller:</u> A commercial entity, licensed to act on behalf of a legal manufacturer and which carries product liability and warranty responsibilities no less onerous than those carried by the legal manufacturer.

3. Normative references (use most current version)

GSI General Specifications: The foundational GS1 standard that defines how identification keys, data attributes and barcodes must be used in business applications. (https://www.gs1.org/barcodes-epcrfid-id-keys/gs1-general specifications).

GS1 Bar Code Verification For Linear Symbols

(https://www.gs1.se/globalassets/gs1-bar-code-verification.pdf).

ISO/IEC 15416:2016: Automatic identification and data capture techniques – Bar code print quality test specification – Linear symbols.

ISO 4892-2 and ISO 4892-3: Plastics – Methods of exposure to laboratory light sources.

ASTM G155: Standard Practice for Operating Xenon Arc Light Apparatus for Exposure of Non-Metallic Materials.

ASTM D5264: Standard Practice for Abrasion Resistance of Printed Materials by the Sutherland Rub Tester.

ASTM G195: Standard Guide for Conducting Wear Tests Using a Rotary Platform Abraser.

ASTM D2860: Standard Test Method for Adhesion of Pressure-Sensitive Tape to Fiberboard at 90° Angle and Constant Stress.

4. Requirements

4.1 <u>Symbology and required information</u>

4.1.1 *GS1-128 compliance*

The asset tag must include a barcode and comply with the GS1-128 symbology as defined in the *GS1 General Specifications* (https://www.gs1.org/barcodes-epcrfid-id-keys/gs1-general-specifications)

4.1.2 Required barcode information

Information included in the barcode must include the following in the listed order, as defined in the *GS1 General Specifications* (GS1 code in parentheses):

- Global Trade Item Number (GTIN) containing the allocated company prefix and item reference (i.e. manufacturer and model) using Application Identifier (01)
- Production date using Application Identifier (11) followed by six numerals signifying year and month and day the appliance was produced. As specified in the *GS1 General Specifications*, if it is not necessary to specify the day, the field must be filled with two zeros (e.g. 11170300 for March 2017)
- The unique serial number for the individual appliance using Application Identifier (21)
- PQS number using Application Identifier (241) followed by seven alphanumeric characters (e.g. 241E003001 for the PQS product number 001 in PQS category E003). The AI (241) identifies a customer part number per the GS1 General Specifications.

Although additional information may be useful for manufacturers, ministries of health, or other entities, this information should be managed separately. The unique identifier serial number can be used to cross-reference between other databases.

4.1.3 Human readable information

The GTIN, serial number, production date and PQS identification (ID) number must also be included as human readable information (HRI) on the asset tag, following the definition and specification of HRI in the *GS1 General Specifications*.

4.1.4 Database connection

The legal manufacturer must supply the GS1 compliant GTIN during dossier submission for each appliance. The legal manufacturer must provide a complete GTIN list or database of all WHO PQS prequalified products produced by the legal manufacturer to WHO PQS on request. The storage and

access to a list of all GTINs from all applicable legal manufacturers will be managed by the WHO PQS.

4.2 Performance

4.2.1 Code quality

Barcodes must have a quality corresponding to the requirements in the *GS1* Barcode Verification For Linear Symbols as well as the *GS1* General Specifications. Requirements in these documents reference ISO/IEC 15416 "Grades". This quality must be verified per ISO/IEC 15416 or a similar methodology if referenced in the GS1 standard.

4.2.2 *Operational lifetime*

The asset tag must have an expected operational lifetime of at least 10 years or the expected life of the appliance to which it is applied, whichever is greater. The asset tag must meet the code quality requirements of *Clause 4.2.1* throughout this operational lifetime.

4.2.3 Durability

The asset tag must remain fully connected or adhered to the appliance without lifting, curling, flagging or peeling and continue to meet the code quality requirements of *Clause 4.2.1* throughout and after being subjected to the following conditions:

- Short-term exposure to extreme temperatures in the range of -20°C to +70°C during shipping and storage prior to installation (verification by accelerated aging testing is recommended)
- Less extreme but long-term exposure to temperatures in the range of -10°C to +43°C throughout the operational lifetime per *Clause* 4.2.2 (verification by accelerated aging testing is recommended)
- Direct UV exposure and extreme humidity (both approaching 0% relative humidity and approaching condensing, 100% relative humidity) throughout the operational lifetime per *Clause 4.2.2* (confirmation of accelerated exposure testing per ISO 4892, ASTM G155 or a similar standard is recommended)
- Abrasion throughout the operational lifetime per Clause 4.2.2
 (confirmation of accelerated abrasion testing per ASTM D5264 for printed asset tags, ASTM G195 for other asset tags, or another similar standard is recommended)
- Periodic contact with water and other liquids including routine cleaning agents throughout the operational lifetime per *Clause* 4.2.2.

Due to the durability requirements placed on asset tags, paper or any other paperboard stock must not be used as label material for the asset tag. Although the durability of the asset tags need not be confirmed through separate testing or verification submitted to the WHO PQS, all durability requirements noted above must be certified by the legal manufacturer or label manufacturer.

4.2.4 Tag location

The asset tag must be located on either the front or the top of the appliance, in a noticeable, visible location, preferably as close to eye-level as possible. If located on the top of the appliance, the height of the appliance must not exceed 1.3 metres.

4.2.5 Application and activation

The asset tag must be permanently adhered or otherwise affixed to the appliance by the legal manufacturer. The purchaser or user must not be required to apply or otherwise activate the asset tag.

4.2.6 Adhesion (if used)

The adhesive (if used to affix the asset tag) must remain permanently affixed to both the label stock (i.e. asset tag material) and the material of the appliance face to which it is applied for the operational lifetime of the appliance per *Clause 4.2.2*. Most pressure sensitive adhesives require time to set completely after being adhered. Seven days is generally more than sufficient time for the bond to reach full strength. After the seven-day setting, the adhesive must create a strong enough bond with the material of the appliance face to which it is applied to pass a standardized bond strength test. Confirmation of bond strength per ASTM D2860 or a similar standard is recommended. The tested bond strength should also be retained for the operational lifetime as required in *Clause 4.2.2* and after being subjected to the durability conditions as noted in *Clause 4.2.3*.

4.2.7 Non-adhesive connection (if used)

If the asset tag is integrated into or affixed to the appliance without use of an adhesive, the materials and construction used must also have operational lifetimes as required in *Clause 4.2.2* and durability as noted in *Clause 4.2.3*.

4.3 Verification

Verification must be confirmed by the legal manufacturer with certification, provided to WHO PQS in writing. It must certify that all specifications in *Clauses 4.2.1* to 4.2.7 have been verified by the legal manufacturer or a third party (such as the asset tag supplier). There is no WHO PQS verification protocol corresponding to this specification.

5. Packaging

Materials used for packaging the finished product are to be free of ozone-depleting compounds as defined in the Montreal Protocol.

6. On-site installation

Not applicable.

7. Product dossier

Not applicable.

8. On-site maintenance

Not applicable.

9. Change notification

The legal manufacturer or reseller is required to advise WHO in writing of all changes which may affect the performance of the product after PQS prequalification has taken place.

10. Defect reporting

The legal manufacturer or reseller is required to advise WHO and the UN purchasing agencies in writing in the event of safety-related product recalls, component defects and other similar events. If requested to do so by WHO/UNICEF, the manufacturer is to submit a report to WHO/UNICEF stating the number of affected systems and the number of component repairs/replacements provided, together with copies of any associated field reports.

Revision history				
Date	Change summary	Reason for change	Approved	