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GS1 Healthcare US[®]

Implementation Guideline

Applying the GS1 Lightweight Messaging Standard for
DSCSA Verification of Returned Product Identifiers

Release 1.1, March 31 2020



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GS1 Healthcare US is an industry group that focuses on driving the adoption and implementation of GS1 Standards in the healthcare industry in the United States to help improve patient safety and supply chain efficiency. GS1 Healthcare US brings together members from all segments of the healthcare industry to address the supply chain issues that most impact healthcare in the United States. Facilitated by GS1 US, GS1 Healthcare US is one of over 30 local GS1 Healthcare user groups around the world that supports the adoption and implementation of global standards developed by GS1.


1 Introduction

Commencing November 27, 2019, the U.S. Drug Supply Chain Security Act (DSCSA) required wholesale distributors to verify the product identifier of returned products before these products can be placed into inventory for resale.¹ The DSCSA defines verification as the process of “determining whether the product identifier affixed to, or imprinted upon on a package, or homogeneous case corresponds to the product identifier assigned to the product by the manufacturer or the repackager.”² A manufacturer who receives a verification request from a repackager, wholesale distributor, or dispenser must respond to that request within 24 hours.³

In preparation, pharmaceutical supply chain stakeholders collaborated with GS1 and GS1 US to develop a verification messaging standard to enable system interoperability and prevent the proliferation of multiple messaging formats. In addition, the GS1 Messaging Standard Workgroup collaborated with the Healthcare Distribution Alliance (HDA) Verification Routing Services (VRS) Taskforce. These efforts produced the [GS1 Lightweight Messaging Standard for Verification of Product Identifiers](#).


The *GS1 Lightweight Messaging Standard* was designed to support requests and responses for verification of product identifiers for serialized pharmaceutical products. It is intended to provide a simple, standardized lightweight messaging framework for asking verification questions and receiving actionable information. Designed to support Verification Routing Services (VRS) systems for DSCSA verification, the messaging standard defines a verification request message and a corresponding output response message.

This guideline defines how to implement that messaging standard for DSCSA verification of returned product identifiers.

 **Important:** As with all GS1 Standards and solutions, this guideline is voluntary, not mandatory. It should be noted that use of the words “must” and “require” throughout this document relate exclusively to technical recommendations for the proper application of the standards to support the integrity of your implementation.

1.1 Document purpose

The purpose of this document is to assist the U.S. pharmaceutical industry in implementing the *GS1 Lightweight Messaging Standard* to support DSCSA product identifier verification for returned products. It provides essential technical information including localization query parameters and settings, the Open API schema, configuration and setup, verification requests and verification responses. **It does not provide any guidance or advice regarding regulatory compliance.**

 **Important:** Each company is individually responsible for meeting all statutory and/or regulatory requirements for their company and their products. Consult with your company’s legal counsel or compliance team (regulatory or quality) for more specific information about current statutory and regulatory requirements applicable to your company and products.

¹ Drug Supply Chain Security Act, Section 582(c)(4)(D). Pub. Law No. 113-54, 127 Stat 587, 613 (2013). Retrieved November 3, 2018 from: <https://www.gpo.gov/fdsys/pkg/PLAW-113publ54/html/PLAW-113publ54.htm>

² Drug Supply Chain Security Act, Section 581(28). Pub. Law No. 113-54, 127 Stat 587, 605 (2013).

³ Drug Supply Chain Security Act, Section 582(b)(4)(C). Pub. Law No. 113-54, 127 Stat 587, 610 (2013).

1.2 Scope

DSCSA requires wholesale distributors to verify the product identifier of returned products before these products can be placed into inventory for resale.⁴ The response message and this guideline were designed to respond to that need.

The DSCSA defines *verify* as “determining whether the product identifier affixed to, or imprinted upon a package, or homogeneous case corresponds to the product identifier assigned to the product by the manufacturer or the repackager.”⁵ Following that definition, the “verified” field in the response message is used to indicate whether a product identifier submitted in the request message matches a product identifier affixed or imprinted by the manufacturer (i.e., true) or not (i.e., false).

! Important: The “verified” field in the response message does not and should not be interpreted as indicating whether a returned product can or should be placed into inventory for resale.

The ultimate decision as to whether a returned product can be placed back in inventory for resale may be subject to and/or dependent on additional regulatory/statutory requirements and/or business considerations. These requirements and considerations are beyond the scope of the response message and this guideline.

Although the response message includes fields for "Reason for Failure" and "Additional Info" to enable manufacturers to communicate more information in the message than just whether the product identifier matches if they so desire, it is assumed trading partners will continue to use whatever communication approaches they deem appropriate for those other regulatory, statutory or business needs.

1.3 Normative references

This implementation guideline is based on GS1 Standards. The specific standards referenced in this guideline are listed below, and the relevant provisions of these standards/specifications are to be considered provisions of this guideline:

- [GS1 General Specifications](#)
- [GS1 Lightweight Messaging Standard for Verification of Product Identifiers](#)
- [GS1 Digital Link](#)

1.4 Non-normative references

Material in this implementation guideline is based on a number of non-normative guidelines and references available from GS1 and GS1 US. The specific guidelines and documents referenced in this guideline are listed below.

- [GS1 US Implementation Guideline: Applying GS1 Standards for DSCSA and Traceability](#)
- [GS1 AIDC Healthcare Implementation Guideline](#)

⁴ Drug Supply Chain Security Act, Section 582(c)(4)(D). Pub. Law No. 113-54, 127 Stat 587, 613 (2013). Retrieved November 3, 2018 from: <https://www.gpo.gov/fdsys/pkg/PLAW-113publ54/html/PLAW-113publ54.htm>

⁵ Drug Supply Chain Security Act, Section 581(28). Pub. Law No. 113-54, 127 Stat 587, 605 (2013).

1.5 Change log

Change log for release 1.1 developed and approved by the Rx Supply Chain Workgroup effective March 31, 2020.

Summary of change	Section
All expiration date examples have been standardized in the future for 2023 with YYMMDD format.	GS1 Standards for DSCSA Product Identifier Data Elements
Security considerations: added "or testing service provider acting on behalf of an authorized trading partner."	GS1 Lightweight Messaging Standard for Verification of Product Identifiers, Security Considerations
New output response messages from the manufacturers with new code values for verificationFailureReason and additionalInfo.	Verification Responses

1.6 Contributors

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2 GS1 Standards for DSCSA Product Identifier Data Elements

DSCSA defines the term “product identifier” as, “a 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 (SNI), lot number, and expiration date of the product.”⁶ Per this definition, a DSCSA product identifier comprises the following four data elements:

- National Drug Code (NDC)
- Serial number
- Batch or lot number
- Expiration date

(When using GS1 Standards for DSCSA implementation, the NDC is represented by a Global Trade Item Number® (GTIN®))

These data elements can be encoded in a GS1 barcode using the following GS1 Application Identifiers (AIs):

DSCSA Product Identifier Data Element	GS1 Application Identifier (AI)
GTIN	AI (01)
Serial Number	AI (21)
Batch or Lot Number	AI (10)
Expiration Date	AI (17)

The concatenated AI element string for encoding those four data elements appears as follows:

(01){gtin}(17){exp}(10){lot}(21){ser}

where {gtin}, {exp}, {lot} and {ser} are placeholders for the actual values.

These data elements can also be expressed within a single web URI using the GS1 Digital Link syntax. The GS1 Digital Link structure (or URI template) for expressing the four data elements in the DSCSA product identifier appears as follows:

<https://other.example.com/gtin/{gtin}/lot/{lot}/ser/{ser}?exp={exp}>

where {gtin}, {exp}, {lot} and {ser} are placeholders for the actual values.

⁶ Drug Supply Chain Security Act. Pub. Law No. 113-54, 127 Stat 587 (2013). Accessed November 1, 2018 from: <https://www.gpo.gov/fdsys/pkg/PLAW-113publ54/html/PLAW-113publ54.htm>

EXAMPLE - Consider a product instance with the following information:

DSCSA Product Identifier Data Element	Sample Value	ENCODED AS
GTIN	00361414567894	AI (01) 00361414567894
Serial Number	400806	AI (21) 400806
Batch or Lot Number	1908642E	AI (10) 1908642E
Expiration Date	July 28, 2023	AI (17) 230728

Those four data elements would be encoded in a barcode using the following concatenated AI element string:

(01)00361414567894(17)230728(10)1908642E(21)400806

And they can be expressed in a web URI format using the following GS1 Digital Link syntax:

`https://other.example.com/gtin/00361414567894/lot/1908642E/ser/400806?exp=230728`

! **Important:** This example illustrates how expiration date is *encoded in GS1 barcodes* and *represented in the GS1 Digital Link syntax* using YYMMDD per GS1 Standards. It is not illustrating how to express expiration date in human-readable presentations on drug packages and/or within systems, which often use YYYYMMDD.

Together, these standardized formats enable users to encode the four DSCSA data elements in a GS1 barcode, express them in a single web URI, and translate between the two. As such, they provide the foundation for automating the verification of product identifiers using barcoded data and the GS1 Lightweight Messaging Standard, as described throughout the remainder of this document.

Note about “00” in the day portion of expiration date

- It is STRONGLY RECOMMENDED that the barcode contain an expiration date that includes a year, month, and non-zero day, encoded in YYMMDD format according to the [GS1 General Specifications](#).
- With respect to verification of saleable returns, the data encoded from returned serialized products may be scanned with “00” day in the day portion of expiration date. In keeping with United States Pharmacopeia (USP) guidance which specifies that an expiration date on a label lacking a day, should be understood to refer to the last day of the month, verification services and responders are expected to appropriately handle this scenario as outlined in Section 6.1.1.1.4 of the [GS1 US Implementation Guideline, R1.2](#).

3 GS1 Lightweight Messaging Standard for Verification of Product Identifiers

The [GS1 Lightweight Messaging Standard for Verification of Product Identifiers](#) is designed to support requests and responses for verification of product identifiers for serialized pharmaceutical products. This standard has been developed and designed to support VRS systems for U.S. DSCSA verification of product identifiers on returned products, the standard defines a verification Request message and a corresponding output response message. It is intended to provide a simple, standardized lightweight messaging framework for asking verification questions and receiving information based on a check of the DSCSA product identifier and associated data.

This standard is the first GS1 technical standard to make use of the new GS1 Digital Link syntax. It enables a basic automated check of a serialized product identifier and the associated expiration date and batch number via a lightweight web-based request/response message pair, initiated by a simple HTTP/HTTPS GET request and returning a lightweight machine-readable response message formatted in JavaScript Object Notation (JSON).


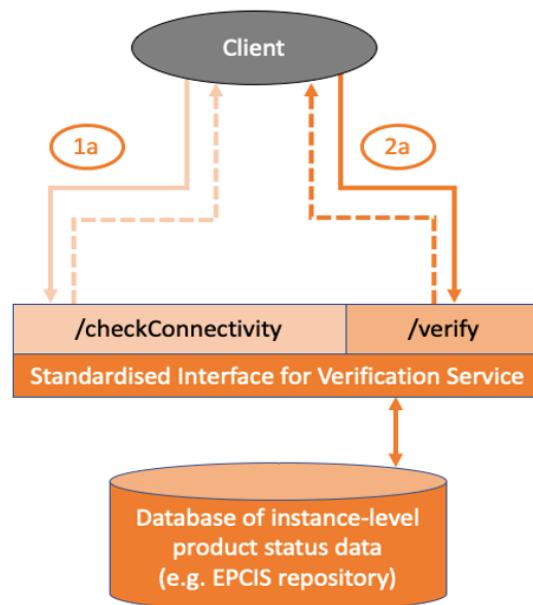
 **Note:** Additional information about the GS1 Lightweight Messaging Standard may be accessed through the following link: <https://www.gs1.org/verification-messaging>

Figure 3-1 Methods by which a client may interact directly with a known VRS system, using either the checkConnectivity method (1a) or the verify method (2a)



In situations where the requestor does not know in advance which VRS to use for a specific GTIN, they may make use of the resolver or lookup directory infrastructure as shown in Figure 3-2. A lookup directory has its own internal database of redirection, which it uses to match against the GTIN within the GS1 Digital Link web URI, to provide a redirection pointer to the appropriate verification service, depending on information configured by the respective brand owner of that GTIN.

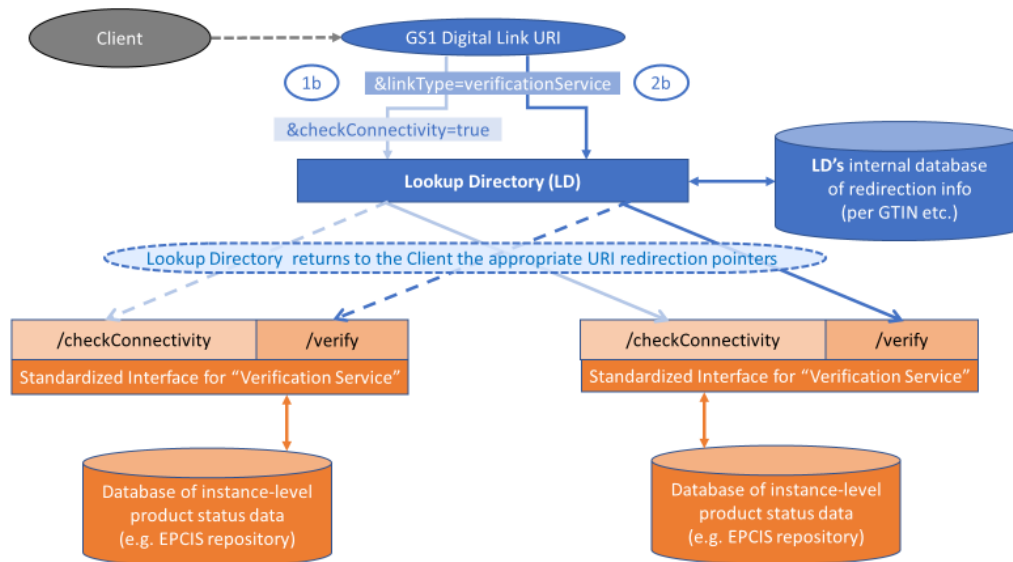
To indicate that the client wants to interact with a verification service, the client specifies within the URI query string a linkType value equal to 'verificationService'.

A lookup directory will redirect the request to the appropriate verification service for that GTIN, and the server for the responder will respond.

The role of the lookup directory (LD) is to provide redirection so that instead of the client maintaining its own lookup table mapping every GTIN to a specific URL of a verification service, a resolver or LD provides up-to-date redirection information.

To distinguish between the two methods (`checkConnectivity` and `verify`) defined for the standardized interface, the client either appends `&checkConnectivity=true` to the GS1 Digital Link URI or does not.

Figure 3-2 A client may use a lookup directory infrastructure for GS1 Digital Links to be redirected to the appropriate verification service for a specific GTIN, as specified by the respective brand owner



3.1 Relationship to GS1 Digital Link

This standard is the first GS1 technical standard to make use of the new GS1 Digital Link syntax. A GS1 Digital Link resolver is already operational at id.gs1.org and can be configured with several typed redirection links by each licensee of a GS1 identification key. One of these typed links can point to the relevant service for verification of product identifiers, as nominated by the respective brand owner.

The team developing the GS1 Digital Link resolver prototype at id.gs1.org are carefully examining HDA requirements and draft specifications for lookup directories to ensure that equivalent functional capabilities can be supported by the GS1 Digital Link resolver at id.gs1.org, including the ability to handle redirection to multiple verification services for the same GTIN concurrently to deal with specific merger and acquisition issues (i.e., when mergers and acquisitions of companies and brands require concurrent operations over a period of time during the changeover period while products with the same GTIN from the previous brand owner and new brand owner coexist within the supply chain).

3.2 Relationship to EPCIS

This standard is independent of GS1 Electronic Product Code Information Services (EPCIS) and does not require the use of EPCIS, although users are encouraged to implement EPCIS to capture their supply chain events and to leverage the EPCIS query interface to retrieve data to support their response to a request for product verification. Although EPCIS event data can record the commissioning or decommissioning of products, as well as current disposition (such as 'recalled') and instance/lot master

data (such as 'expiration date'), it does not provide a sufficiently convenient interface to perform a simple verification check of product identifiers at batch or serial level.

3.3 Security considerations

The request includes a Requestor Global Location Number (GLN). It is expected that prior to honoring any requests, a verification service or company building their own requesting or responding services will take steps to ensure that the requestor is an authorized trading partner or testing service provider acting on behalf of an authorized trading partner, who has a justification for using the service.

4 Localization Parameters and Settings

The [GS1 Lightweight Messaging Standard for Verification of Product Identifiers](#) is structured to promote re-use and extension to other industry sectors in all geographic regions. The combination of `linkType` and `context` parameter values in the GS1 Digital Link (Web URI) query string for a verification request provide localization parameters that can tailor the scope of the business rules.

4.1 Definition of linkType

`linkType` is a required query parameter included within a URI query string to specify a preferred type of information or service requested by the client. A resolver or lookup directory service can then use the value specified by `linkType` to select which link(s) to return to the client.

Usage of linkType

For U.S. DSCSA verification of returned product identifiers, `linkType` is a required query parameter in the URI query string. To specify the information service for U.S. DSCSA verification of returned product identifiers, `linkType` must be set to `'verificationService'`.

4.2 Definition of context

`context` is a required query parameter included within a URI query string to provide supporting context information for the scope of the information service indicated by `linkType`.

The `context` query parameter is used in conjunction with the `linkType` query parameter. It has meaning within that `linkType`. Within a `linkType` value of `'verificationService'`, it provides a verification service with `context` about the request, indicating a particular profile, which may indicate whether the verification should be performed in accordance with the rules and semantics of a specific jurisdiction or regulatory scheme (as is the case for `context = dscsaSaleableReturn`).

Usage of context

! Important: For U.S. DSCSA verification of returned product identifiers, `context` is a required query parameter in the URI query string. In this specification, set the value of `linkType` to `'verificationService'` and then set the value of `context` to `'dscsaSaleableReturn'` to ensure that the verification service that receives the request understands that it should use the configuration, rules and interpretation for U.S. DSCSA verification of product identifiers for returned pharmaceutical products.

5 Overview of OpenAPI Schema (including JSON) for Verification Request & Response

The GS1 Lightweight Verification Messaging Standard is a machine-readable specification of the verification message REST interface, using the OpenAPI Specification™ (OAS™).⁷ It includes JSON Schema components for validating the structure of the request and response messages in an automated manner to support conformance testing.

This chapter provides high-level information about the schema. To that end, this chapter highlights key structures of the OpenAPI Specification and how they are applied within the GS1 Lightweight Verification Messaging Standard to bring attention to important definitions that should be adhered to by verification service implementations.

- For additional information about the GS1 Lightweight Verification Messaging Standard, see:
 - [Lightweight Verification Messaging Standard v1.0.2](#) (Jan 2019)
 - [Lightweight Verification Messaging OpenAPI](#) (Jan 2019)
 - [GS1US Lightweight Verification Messaging OpenAPI](#) (Mar 2020)
- For additional information about the OpenAPI Specification, visit:
 - [OpenAPI Initiative](#)
 - [OpenAPI Specification](#)

5.1 Available endpoints

In OpenAPI Specification terms, `paths` are endpoints or resources that the API exposes.

There are 2 available paths in [GS1 Lightweight Verification Messaging Standard](#): `/checkConnectivity` and `/verify`.

- The `/checkConnectivity` path of a verification service enables a check of system connectivity with the verification service and returns appropriate HTTP status codes.
- The `/verify` path of a verification service implements the verification of the product identifiers subject to the rules defined by the context query parameter such as `'dscsaSaleableReturn'`.

⁷ OpenAPI Specification and OAS and their respective logos, are trademarks of The Linux Foundation®. Linux is a registered trademark of Linus Torvalds.

Figure 5-1 Two API paths defined in the global paths section of the API specification

```

1 {
2   "openapi": "3.0.0",
3   "info": {
4     "version": "1.0.0",
5     "title": "GS1 Verification Messaging Standard",
6     "contact": {
7       "name": "GS1",
8       "url": "https://www.gs1.org",
9       "email": "gsmp@gs1.org"
10    },
11    "description": "This the API specification for peer-to-peer communication
12      between Verification Router Services or VRS"
13  },
14  "servers": [{
15    "url": "https://vrs.example.com/gateway/placeholder"
16  }],
17  "paths": {
18    "/checkConnectivity": {
19      "get": {
20        "summary": "Check connectivity to the VRS"
21      }
22    },
23    "/verify/gtin/{gtin}/lot/{lot}/ser/{ser}": {
24      "get": {
25        "summary": "Verify product information"
26      }
27    }
28  }
29 }

```

5.2 Operations

In OpenAPI Specification terms, operations are HTTP methods used to access and manipulate the paths. For each path, one or more operations such as GET, POST, or DELETE can be defined, but only one instance of an operation (HTTP method) can be defined for a path.

Both the `checkConnectivity` and `verify` paths of a verification service are defined to have a single operation: GET.

Figure 5-2 HTTP GET method defined for the two API paths, /checkConnectivity and /verify

```

1 {
2   "openapi": "3.0.0",
3   "info": {
4     "version": "1.0.0",
5     "title": "GS1 Verification Messaging Standard",
6     "contact": {
7       "name": "GS1",
8       "url": "https://www.gs1.org",
9       "email": "gsmp@gs1.org"
10    },
11    "description": "This the API specification for peer-to-peer communication
12                  between Verification Router Services or VRS"
13  },
14  "servers": [{
15    "url": "https://vrs.example.com/gateway/placeholder"
16  }],
17  "paths": {
18    "/checkConnectivity": {
19      "get": {
20        // ...
21      }
22    },
23    "/verify/gtin/{gtin}/lot/{lot}/ser/{ser}": {
24      "get": {
25        // ...
26      }
27    }
28  }
29 }

```

5.3 Parameters

In OpenAPI Specification, parameters are defined in the parameters section of an operation or path. A parameter description includes the following:

- Parameter name
- Location of where the parameter appears (i.e., whether it's included in the path (`in: path`) or the query string (`in: query`))
- Data type of the parameter as defined by either schema or content
- Other parameter attributes (such as parameter description) and whether the parameter is required or optional.

Path and query are two types of parameters defined in the OpenAPI Specification:

- Path parameters form the variable part of a URI path and they partition the resource of the path. The location of path parameters are denoted by `in: path` in the parameter section of the OpenAPI Specification.

Figure 5-3 The three path parameters that partition the resources of the /verify path to a specific gtin, lot and ser

```

"/verify/gtin/{gtin}/lot/{lot}/ser/{ser}": {
  "get": {
    "tags": [
    ],
    "description": "Verify a saleable return",
    "parameters": [
      {
        "name": "gtin",
        "in": "path",
        "description": "Global Trade Item Number",
        "required": true,
        "schema": {
          "$ref": "#/components/schemas/gtin"
        }
      },
      {
        "name": "lot",
        "in": "path",
        "description": "Lot/Batch Number",
        "required": true,
        "schema": {
          "$ref": "#/components/schemas/lotNum"
        }
      },
      {
        "name": "ser",
        "in": "path",
        "description": "Serial Number",
        "required": true,
        "schema": {
          "$ref": "#/components/schemas/serialNumber"
        }
      }
    ]
  }
}

```

Query parameters appear at the end of the request URL after a question mark ('?') followed by name value pair (name=value) separated by ampersands ('&'). The location of query parameters are denoted by the in: query in the parameter section of the OpenAPI Specification.

Here is an example taken from Figure 1-5 of the [GS1 Lightweight Verification Messaging Standard](#) illustrating a /verify path with query parameters exp, linkType, context, reqGLN and corrUUID:

```

GET https://verificationService.example.com/verify/gtin/{gtin}/lot/{lot}/ser/{ser}
?exp={exp}&linkType=verificationService&context=dscsaSaleableReturn
&reqGLN={reqGLN}&corrUUID={correlationUUID}

```

Figure 5-4 How the query parameters are defined for /verify in the GS1 Lightweight Verification Messaging Standard

```

"/verify/gtin/{gtin}/lot/{lot}/ser/{ser}": {
  "get": {
    "tags": [
    ],
    "description": "Verify a saleable return",
    "parameters": [{
      "name": "gtin",
      "in": "path",
      "description": "Global Trade Item Number",
      "required": true,
      "schema": {
      }
    }
  ],
  {
  },
  {
  },
  {
  },
  {
    "name": "exp",
    "in": "query",
    "description": "Expiry",
    "required": true,
    "schema": {
      "$ref": "#/components/schemas/expiryDate"
    }
  },
  {
    "name": "linkType",
    "in": "query",
    "description": "Typed Link",
    "required": true,
    "schema": {
      "$ref": "#/components/schemas/linkType"
    }
  }
  },
},

```

```

    "name": "context",
    "in": "query",
    "description": "Verification Context",
    "required": true,
    "schema": {
      "$ref": "#/components/schemas/context"
    }
  },
  {
    "name": "reqGLN",
    "in": "query",
    "description": "Requestor GLN",
    "required": true,
    "schema": {
      "$ref": "#/components/schemas/gln"
    }
  },
  {
    "name": "corrUUID",
    "in": "query",
    "description": "Correlation UUID",
    "required": true,
    "schema": {
      "$ref": "#/components/schemas/uuid"
    }
  }
],

```

Parameter definitions include `schema` objects to describe the structure and syntax of the parameters. Schema definitions facilitate robust validation and implementations of the API. Implementations of the verification messaging service for product identifiers will be validated against the schemas defined in the [GS1 Lightweight Verification Messaging Standard](#).

Figure 5-5 shows the `gln` schema definition which specifies data type, minimum length, maximum length, regular expression template for the string value and provides an example. This `gln` schema definition is one of many `schema` definitions included in the components section of the [GS1 Lightweight Verification Messaging Standard](#).

Figure 5-5 GLN schema definition

```

"schemas": {
  "gln": {
    "type": "string",
    "minLength": 13,
    "maxLength": 13,
    "example": "9071404000002",
    "pattern": "^\\d{13}$"
  }
},

```

5.4 Components and schema data

Schema definitions shared by multiple parameters and response properties are defined in the `components` section of the OpenAPI Specification and referenced in the schema parameter definition using `$ref`. This consolidates the shared and reusable definitions in one section of the OpenAPI Specification.

Figure 5-6 GLN schema being referenced in the parameter definition of `reqGLN` for `/verify`

```

"/verify/gtin/{gtin}/lot/{lot}/ser/{ser}": {
  "get": {
    "tags": [
    ],
    "description": "Verify a saleable return",
    "parameters": [{
      "name": "gtin",
      "in": "path",
      "description": "Global Trade Item Number",
      "required": true,
      "schema": {
        "$ref": "#/components/schemas/gtin"
      }
    }
  ],
  {
  },
  {
  },
  {
  },
  {
  },
  {
  },
  {
  },
  {
  },
  {
  },
  {
  },
  {
    "name": "reqGLN",
    "in": "query",
    "description": "Requestor GLN",
    "required": true,
    "schema": {
      "$ref": "#/components/schemas/gln"
    }
  },
  {
  },
  {
  }
},
],

```


Figure 5-7 GLN schema being referenced by the responderGLN properties in the ConnectivityCheckResponse

```

"ConnectivityCheckResponse": {
  "required": [
    "responderGLN"
  ],
  "properties": {
    "responderGLN": {
      "$ref": "#/components/schemas/gln"
    }
  }
},

```

Figure 5-8 GLN schema being referenced by the responderGLN properties in the PositiveVerificationResponse

```

"PositiveVerificationResponse": {
  "required": [↔],
  ],
  "properties": {
    "verificationTimestamp": {↔},
    },
    "correlationUUID": {↔},
    },
    "responderGLN": {
      "$ref": "#/components/schemas/gln"
    },
    "data": {↔},
    }
  }
},

```

Figure 5-9 GLN schema being referenced by the responderGLN properties in the NegativeVerificationResponse

```

"NegativeVerificationResponse": {
  "required": [↔],
},
"properties": {
  "verificationTimestamp": {↔},
},
"correlationUUID": {↔},
},
"responderGLN": {
  "$ref": "#/components/schemas/gln"
},
"data": {↔},
}
}

```

Figure 5-10 Common schema and response structures shared by multiple API operations

```

"components": {
  "schemas": {
    "gln": {↔},
  },
  "gtin": {↔},
},
"lotNum": {↔},
},
"serialNumber": {↔},
},
"expiryDate": {↔},
},
"uuid": {↔},
},
"timestamp": {↔},
},
"linkType": {↔},
},
"context": {↔},
},
"positiveVerificationStatus": {↔},
},
"negativeVerificationStatus": {↔},
},
"verificationFailureReason": {↔},
},
"additionalInformation": {↔},
},
}

```

5.5 Responses

An API specification defines the structure of the response for each of the operations in the API. The response includes the HTTP status code(s) and the content of the data returned in the response body. The [GS1 Lightweight Verification Messaging Standard](#) defines a `ConnectivityCheckResponse` to a successful response to the `/checkConnectivity` GET operation.

Figure 5-11 Response definition for `/checkConnectivity` GET operation

```

"paths": {
  "/checkConnectivity": {
    "get": {
      "tags": [
        "Test"
      ],
      "description": "Test connection to endpoints",
      "parameters": [{↔}],
      "responses": {
        "200": {
          "description": "A response code of 200 means the request was successful and details about the response can be found in the body of the response. Only a 200 response will issue a JSON payload.",
          "content": {
            "application/json": {
              "schema": {
                "$ref": "#/components/schemas/ConnectivityCheckResponse"
              }
            }
          }
        },
        "400": {↔},
        "401": {↔},
        "403": {↔},
        "404": {↔},
        "405": {↔},
        "408": {↔},
        "500": {↔},
        "502": {↔}
      }
    }
  }
}

```

For the /verify GET operation, a successful response can either be based on PositiveVerificationResponse or a NegativeVerificationResponse.

Figure 5-12 Response definition for the /verify GET operation

```

"/verify/gtin/{gtin}/lot/{lot}/ser/{ser}": {
  "get": {
    "tags": [
    ],
    "description": "Verify a saleable return",
    "parameters": [
    ],
    "responses": {
      "200": {
        "description": "A response code of 200 means the request was
          successful and details about the response can be found in the
          body of the response. Only a 200 response will issue a JSON
          payload.",
        "content": {
          "application/json": {
            "schema": {
              "oneOf": [
                {
                  "$ref": "#/components/schemas/PositiveVerificationResponse"
                },
                {
                  "$ref": "#/components/schemas/NegativeVerificationResponse"
                }
              ]
            }
          }
        }
      }
    }
  }
}

```

6 Configuration and Setup for Connectivity Testing

6.1 Making a connectivity request

Prior to performing a verification request, users can perform a connectivity check to confirm that a web connection to the corresponding verification service exists, and that the verification service is online and responding. Connectivity check is purely a system function that can be performed occasionally to ensure web connections are still valid and active.

The `checkConnectivity` operation of a verification service enables a check for connectivity with the verification service that returns appropriate HTTP status codes. If the Requestor GLN (`reqGLN`) was not recognized, the verification service can respond with an HTTP 401 'Unauthorized' response, provided that it receives the request. If the Requestor GLN (`reqGLN`) is not permitted to make requests, the verification service can respond with an HTTP 403 'Forbidden' response.

Since the verification service provider for a GTIN may change due to changes in product ownership such as product divestiture or company merger and acquisition (M&A), or due to solution change in serial number repository or VRS provider, the lookup directory may contain multiple verification service links for the same GTIN. The lookup directory entries for the same GTIN are differentiated in the lookup directory by non-overlapping `startExpDate` and `endExpDate`. For the purpose of checking system availability of verification service for a GTIN, a connectivity request can be made to each verification service link matching a GTIN.

The `checkConnectivity` operation of a verification service is a simple HTTPS GET request wherein the URI path information ends with `/checkConnectivity` and the following four required query parameters are specified in the URI query string:

- GTIN (for routing purposes)
- Requestor GLN (to uniquely identify the requestor)
- Link type (indicates specific type of information or service)
- Context (indicates the specific scope of service within the verification service)

6.2 Example of a JSON connectivity test

The example below illustrates a sample JSON connectivity test with a known verification service with the context of verification of `dscsaSaleableReturn`. The HTTP header `Accept:` with value `application/json` is used to indicate to the verification service that the client would like to receive a response to the connectivity check in JavaScript Object Notation (JSON) format.

```
GET
https://verificationService.example.com/checkConnectivity?gtin=01234567890128&reqGLN=0321012345676&linkType=verificationService&context=dscsaSaleableReturn
Accept: application/json
```

6.3 Example of a successful JSON connectivity response

The response to such a connectivity check request is an HTTP response containing a JSON body payload formatted as follows:

```
{
  "responderGLN": "{responderGLN}"
}
```

If the responder GLN were 012341234567, the following JSON body would be expected in the response if the connection is successful and returns an HTTP 200 status code:

```
{  
  "responderGLN": "012341234567"  
}
```

6.4 Example of a successful JSON connectivity response with HTTP status code 200

```
HTTP 1.1 200 OK  
Cache-Control: private, no-cache  
Content-Type: application/json  
{  
  "responderGLN": "012341234567"  
}
```

6.5 Example of a failed JSON connectivity response with an HTTP status code of 503

If no successful connection can be established, appropriate HTTP status codes and helpful descriptions will be returned, as appropriate.

```
HTTP 1.1 503 Service Unavailable. System is undergoing maintenance or is  
otherwise temporarily unavailable for API queries.  
Cache-Control: private, no-cache  
Content-Type: application/json
```

7 Configuration and Setup for a DSCSA Verification Request

7.1 Making a DSCSA verification request

Using the GS1 Lightweight Messaging Standard, an `HTTPS GET` request can be made to request verification of a DSCSA product identifier on a given product by specifying `linkType=verificationService` and by specifying the verification `context=dscsaSaleableReturn`, as well as the following details of the request supplied via the URI query string:

- Requestor GLN (to uniquely identify the requestor)
- Correlation UUID (universally unique identifier, uniquely generated by the requestor)

Although a web request typically returns a synchronous response, both the request and corresponding response may also be archived for audit purposes. It is for this reason that both share the same Correlation UUID, in order that each request may be matched with the corresponding response even when archived.

The Requestor GLN may be used by a verification service as an input to an access control decision, where access may only be granted to recognized values of Requestor GLN, and requests with unrecognized values of Requestor GLN may be redirected to a registration page (via an `HTTP 403 'Forbidden'` response) through which the requestor can register for access by providing appropriate credentials and justification.

The full GS1 Digital Link Web URI template for a verification request for a DSCSA product identifier on a returned product is therefore generated by adding the following additional query parameters to the URI query string:

```
&linkType=verificationService
&context=dscsaSaleableReturn
&reqGLN={RequestorGLN}
&corrUUID={CorrelationUUID}
```

This results in the following URI template:

```
https://other.example.com/gtin/{gtin}/lot/{lot}/ser/{ser}?exp={exp}&linkType=verificationService&context=dscsaSaleableReturn&reqGLN={Requestor GLN}&corrUUID={Correlation UUID}
```

A resolver for GS1 Digital Link URI could be configured to redirect a GS1 Digital Link URI with these additional parameters in the query string (and the absence of the `checkConnectivity=true` parameter) to the verify method/operation of the appropriate verification service specified by the respective brand owner and licensee of that GTIN.

- ✔ **Note:** Both Requestor GLN and Correlation UUID are explicitly required for the `dscsaSaleableReturn` context but may not be relevant to other uses of the GS1 Lightweight Messaging Standard in other sectors or regulatory jurisdictions.

7.2 Example of a JSON verification request

The examples below use the following values for GTIN, batch or lot number, serial number and expiration date, Requestor GLN, Correlation UUID and context:

- **GTIN:** 00361414567894

- **Batch or lot number:** 1908642E
- **Serial number:** 400806
- **Expiration date:** 230728
- **linkType:** verificationService
- **context:** dscsaSaleableReturn
- **Requestor GLN:** 0321012345676
- **Correlation UUID:** 21EC2020-3AEA-4069-A2DD-08002B30309D

Inputting these values into the full GS1 Digital Link Web URI template shown above produces the following URI:

```
https://other.example.com/gtin/00361414567894/lot/1908642E/ser/400806?exp=230728&linkType=verificationService&context=dscsaSaleableReturn&reqGLN=0321012345676&corrUUID=21EC2020-3AEA-4069-A2DD-08002B30309D
```

By making a simple HTTPS GET request for such web URIs, the requestor would be redirected to the respective brand owner's verification service (provided this is known to a resolver for GS1 Digital Link Web URIs), which could then use the translation functions to extract the data, convert it to a searchable format, and then process the verification request by searching their systems and issuing an appropriate response.

The example below illustrates a sample JSON verification request with the `context` of `dscsaSaleableReturn` when communicating with a known verification service. The HTTP header `Accept:` with value `application/json` is used to indicate to the verification service that the client would like to receive a response to the verification request in JavaScript Object Notation (JSON) format.

GET

```
https://verificationService.example.com/verify/gtin/01234567890128/lot/1908642E/ser/400806?exp=230728&linkType=verificationService&context=dscsaSaleableReturn&reqGLN=032101234567&corrUUID=21EC2020-3AEA-4069-A2DD-08002B30309D
```

```
Accept: application/json
```

```
```\n
```



## 8 Verification Responses

### 8.1 Interpretation of the 'verified' field

DSCSA requires wholesale distributors to verify the product identifier of returned products before these products can be placed into inventory for resale.<sup>8</sup> The response message and this guideline were designed to respond to that specific need.

The DSCSA defines *verify* as "determining whether the product identifier affixed to, or imprinted upon a package, or homogeneous case, corresponds to the product identifier assigned to the product by the manufacturer, or the repackager."<sup>9</sup> Following that definition, the "verified" field in the output response message is used to indicate whether a product identifier submitted in the request matches a product identifier affixed or imprinted by the manufacturer (i.e., true) or not (i.e., false).

**! Important: The "verified" field in the output response message does not, and should not be interpreted, as indicating whether a returned product can, or should be placed into inventory for resale.**

The ultimate decision as to whether a returned product can be placed back in inventory for resale may be subject to, and/or dependent on additional regulatory/statutory requirements and/or business considerations. These requirements and considerations are beyond the scope of the output response message and this guideline. Although the output response message includes fields for "Reason for Failure" and "Additional Info" to enable manufacturers to communicate additional information in the message, than just whether the product identifier matches if they so desire, it is assumed trading partners will continue to use whatever communication approaches they deem appropriate for those other regulatory, statutory or business needs.

### 8.2 Syntax of verification response

- JSON syntax will be used to respond to all verification requests.
- Verification responses SHALL, at a minimum, indicate:
  - Responder GLN
  - Correlation UUID indicated by the requestor in the original verification request
  - Whether the product identifier was verified (true) or not verified (false)
  - Where NOT verified, indication of the reason for non-verification via the value of the `verificationFailureReason` parameter using one of the following code values:

<sup>8</sup> Drug Supply Chain Security Act, Section 582(c)(4)(D). Pub. Law No. 113-54, 127 Stat 587, 613 (2013). Retrieved November 3, 2018 from: <https://www.gpo.gov/fdsys/pkg/PLAW-113publ54/html/PLAW-113publ54.htm>

<sup>9</sup> Drug Supply Chain Security Act, Section 581(28). Pub. Law No. 113-54, 127 Stat 587, 605 (2013).

Code value for verificationFailureReason	Meaning
"Manufacturer_policy"	Pharmaceutical manufacturers may have different internal policies, which will return a Verified true, or false for the same conditions or determines whether to return additional information with the verification.
"No_match_GTIN_Serial"	No match between GTIN and serial number <i>(For a serialized product, if GTIN and serial number do not match, there is no need to check whether lot or expiration date match)</i>
"No_match_GTIN_Serial_Lot_Expiry"	No match between (GTIN and serial number) and lot number and expiration date
"No_match_GTIN_Serial_Lot"	No match between (GTIN and serial number) and lot number
"No_match_GTIN_Serial_Expiry"	No match between (GTIN and serial number) and expiration date
"No_reason_provided"	No reason provided
"Not_for_re-distribution"	The pharmaceutical manufacturer notifies the requestor that the product is suspect and not for redistribution

- To enhance auditability, a verification timestamp is included in the verification response to record the date and time the manufacturer responded to the verification request.
- OPTIONAL additional information may be provided via the additionalInfo parameter.
  - The value of the additionalInfo parameter is not a free text description, but rather a code value from the following table:

Code value for additionalInfo	Meaning
"Expired"	The product has an expiration date which is in the past
"Recalled"	The product has been recalled or withdrawn
"Suspect"	The product's authenticity or integrity is considered suspect by the responder

### 8.3 Examples of verification responses based on U.S. supply chain business scenarios

Each example business scenario presented in this chapter starts with the wholesale distributor (herein referred to as “requestor”) entering the DSCSA product identifier marked on a returned serialized product (e.g., scan the barcode; key in; interface; etc.), and then requesting verification of the product identifier. VRS then routes the request to the appropriate manufacturer (herein referred to as “responder”) for verification of the product identifier against their repository.

#### Example of Saleable Return Response Scenarios

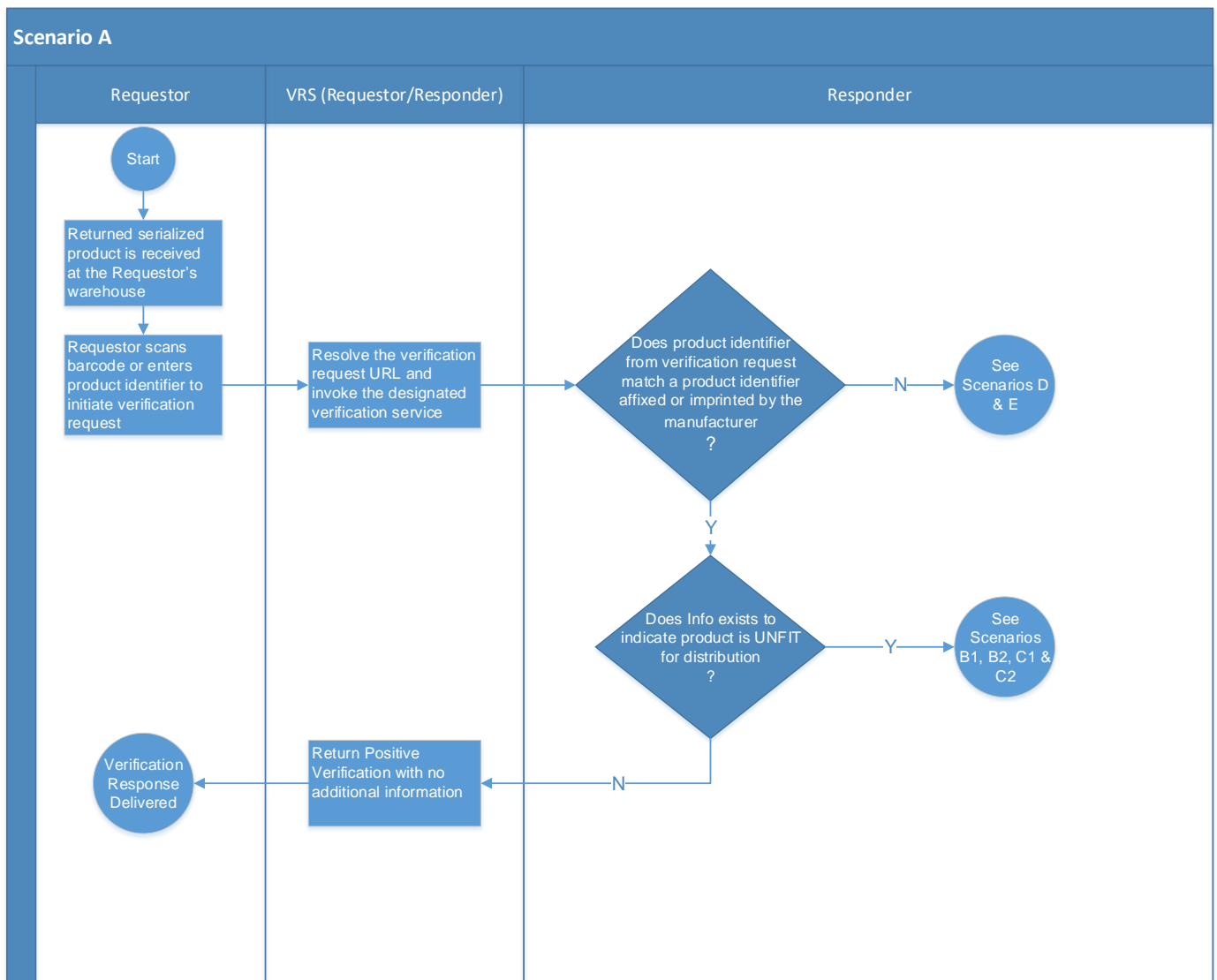
Scenario number	Logic inside VRS solution provider’s software  Scenario description	In VRS provider’s verification conditions		Messaging Standard - Output Response		
		PI match	Info exists to indicate product is <b>UNFIT for distribution</b>	Verified	verificationFailure Reason	additionalInfo
Scenario A	Product identifier matches AND manufacturer has <b>NO</b> information to indicate that product is UNFIT for distribution	Yes	No	True		
Scenario B1	Product identifier matches, AND manufacturer has PROVIDED additional info, indicating the product is recalled or expired and therefore UNFIT for distribution	Yes	Yes	True *** based on manufacturer internal policy		Recalled or Expired *
Scenario B2	Product identifier matches, AND manufacturer has PROVIDED additional info, indicating that the product is recalled or expired and therefore UNFIT for distribution	Yes	Yes	False *** based on manufacturer internal policy	Manufacturer_policy **	Recalled or Expired *
Scenario C1	Product identifier matches, AND manufacturer has PROVIDED additional info, indicating that product is suspect and therefore UNFIT for distribution	Yes	Yes	False *** based on manufacturer internal policy	Not_for_re-distribution**	Suspect
Scenario C2	Product identifier matches, AND manufacturer HAS additional info to suggest that product is UNFIT for distribution	Yes	Yes	False *** based on manufacturer internal policy	Manufacturer_policy **	
Scenario D	Product identifier does <b>NOT</b> match AND manufacturer chooses NOT to provide a reason for verification failure	No		False	No_reason_provided	
Scenario E	Product identifier does <b>NOT</b> match, AND manufacturer provides a reason for verification failure	No		False	<b>One of the following can be provided:</b> No_match_GTIN_Serial No_match_GTIN_Serial_Lot_Expiry No_match_GTIN_Serial_Lot No_match_GTIN_Serial_Expiry	

Additional output responses: Augment the enumeration list for "verificationFailure Reason" to include **"Manufacturer\_policy"**\*\*, and **"Not\_for\_re-distribution"**\*\*. Additionally, need to include "Expired" \* to the enumeration list for "additionalInfo". See appendix 11.1 for details on the Open API Schema changes.

\*\*\* Pharmaceutical manufacturers may have different internal policies, which will return a Verified True, or False for the same conditions. Internal policies will also allow manufacturers to leave additionalInfo field blank.

### 8.4 Scenario A

In scenario A, the product identifier matches a value in the responder's repository. No information exists to indicate the product is Unfit for Distribution and the Output Response of Verified = true is provided back to the requestor.

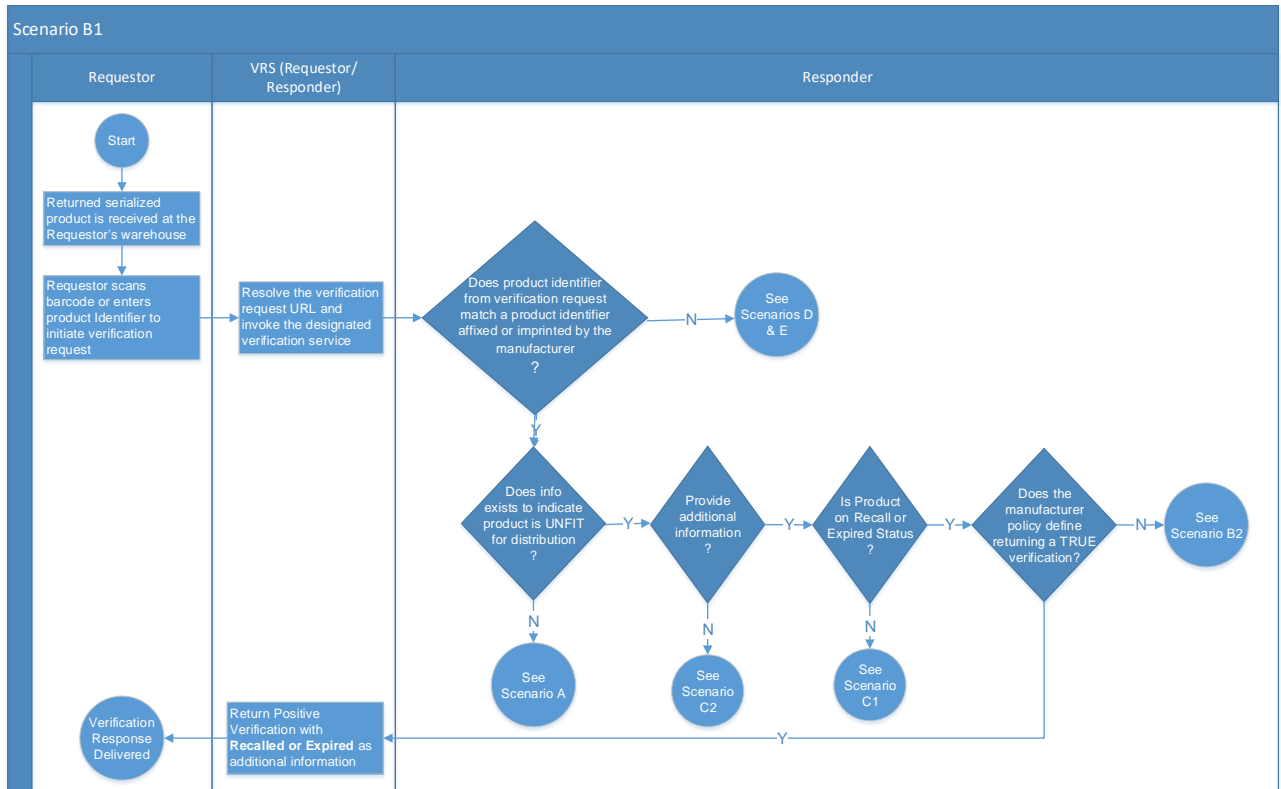


The example below illustrates a sample JSON response to a request for verification of a returned product identifier following positive verification, with no additional information. In this example, the Correlation UUID is 21EC2020-3AEA-4069-A2DD-08002B30309D, and the GLN of the manufacturer responding to the verification request is 0312231245676.

```
HTTP 1.1 200 OK
Cache-Control: private, no-cache
Content-Type: application/json
{
 "verificationTimestamp": "2018-08-14T23:29:00.000-08:00",
 "responderGLN": "0312231245676",
 "data" : {
 "verified": true
 },
 "corrUUID": "21EC2020-3AEA-4069-A2DD-08002B30309D"
}
```

## 8.5 Scenario B1

In scenario B1, the product identifier matches a value in the responder’s repository, and the responder has reason to believe that the product is recalled/withdrawn or expired. The responder returns a true verification response (based on the manufacturer internal policy) and provides “Recalled” or “Expired” as additional information in the Output Response.



The example below illustrates a sample JSON response to a request for verification of a returned product identifier following a positive verification response, which includes `Recalled` as additional information. In this example, the Correlation UUID is `21EC2020-3AEA-4069-A2DD-08002B30309D`, and the GLN of the manufacturer responding to the verification request is `0312231245676`.

```

HTTP 1.1 200 OK
Cache-Control: private, no-cache
Content-Type: application/json
{
 "verificationTimestamp": "2018-08-14T23:29:00.000-08:00",
 "responderGLN": "0312231245676",
 "data" : {
 "verified": true,
 "additionalInfo": "Recalled"
 },
 "corrUUID": "21EC2020-3AEA-4069-A2DD-08002B30309D"
}

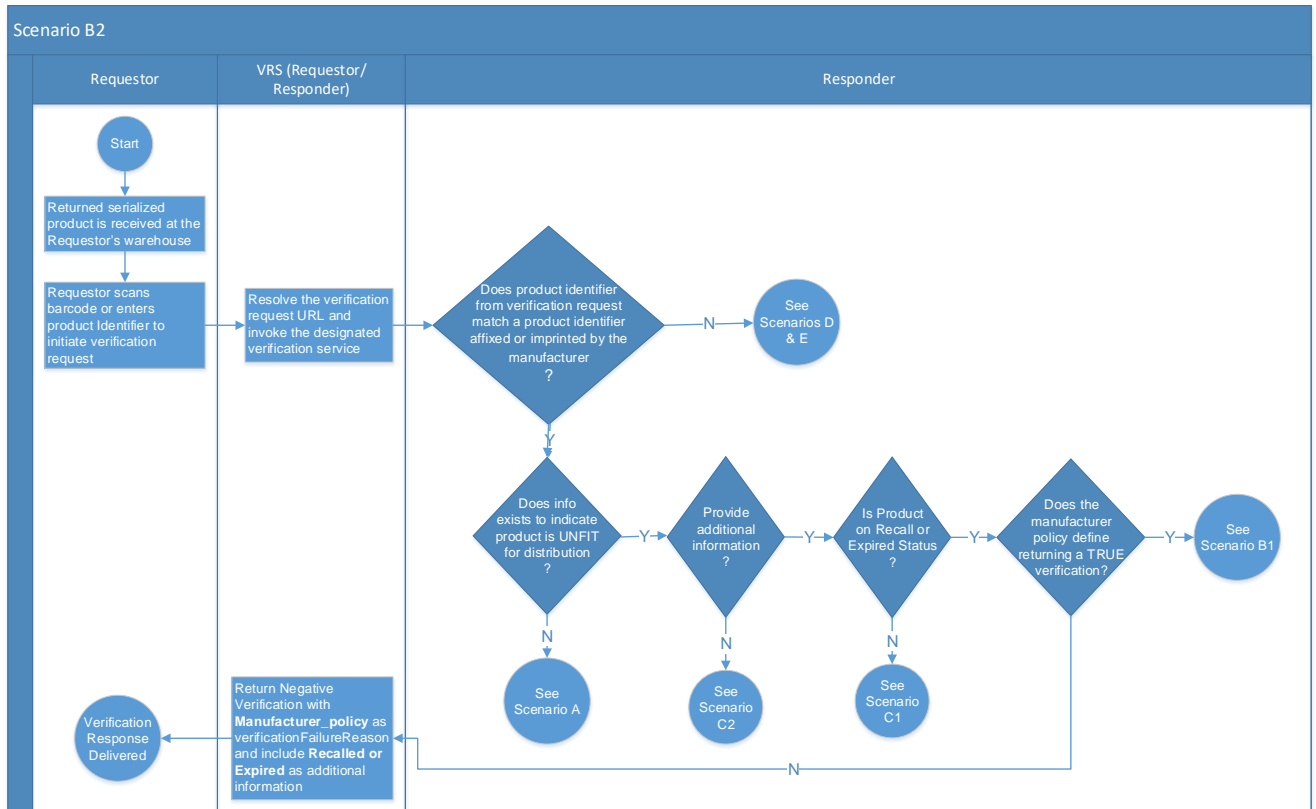
```

The example below illustrates a sample JSON response to a request for verification of a returned product identifiers following a positive verification, which includes `Expired` as additional information. In this example, the Correlation UUID is `21EC2020-3AEA-4069-A2DD-08002B30309D`, and the GLN of the manufacturer responding to the verification request is `0312231245676`.

```
HTTP 1.1 200 OK
Cache-Control: private, no-cache
Content-Type: application/json
{
 "verificationTimestamp": "2018-08-14T23:29:00.000-08:00",
 "responderGLN": "0312231245676",
 "data" : {
 "verified": true,
 "additionalInfo": "Expired"
 },
 "corrUUID": "21EC2020-3AEA-4069-A2DD-08002B30309D"
}
```

## 8.6 Scenario B2

In scenario B2, the product identifier matches a value in the responder’s repository, and the responder has reason to believe that the product is recalled/withdrawn or expired. The responder returns a false verification response (based on the manufacturer internal policy) and provides “Recalled” or “Expired” as additional information in the Output Response



The example below illustrates a sample JSON response to a request for verification of a returned product identifier following failure of verification, which includes `Recalled` as additional information. In this example, the Correlation UUID is `21EC2020-3AEA-4069-A2DD-08002B30309D`, and the GLN of the manufacturer responding to the verification request is `0312231245676`.

```

HTTP 1.1 200 OK
Cache-Control: private, no-cache
Content-Type: application/json
{
 "verificationTimestamp": "2018-08-14T23:29:00.000-08:00",
 "responderGLN": "0312231245676",
 "data" : {
 "verified": false,
 "verificationFailureReason": "Manufacturer_policy",
 "additionalInfo": "Recalled"
 },
 "corrUUID": "21EC2020-3AEA-4069-A2DD-08002B30309D"
}

```

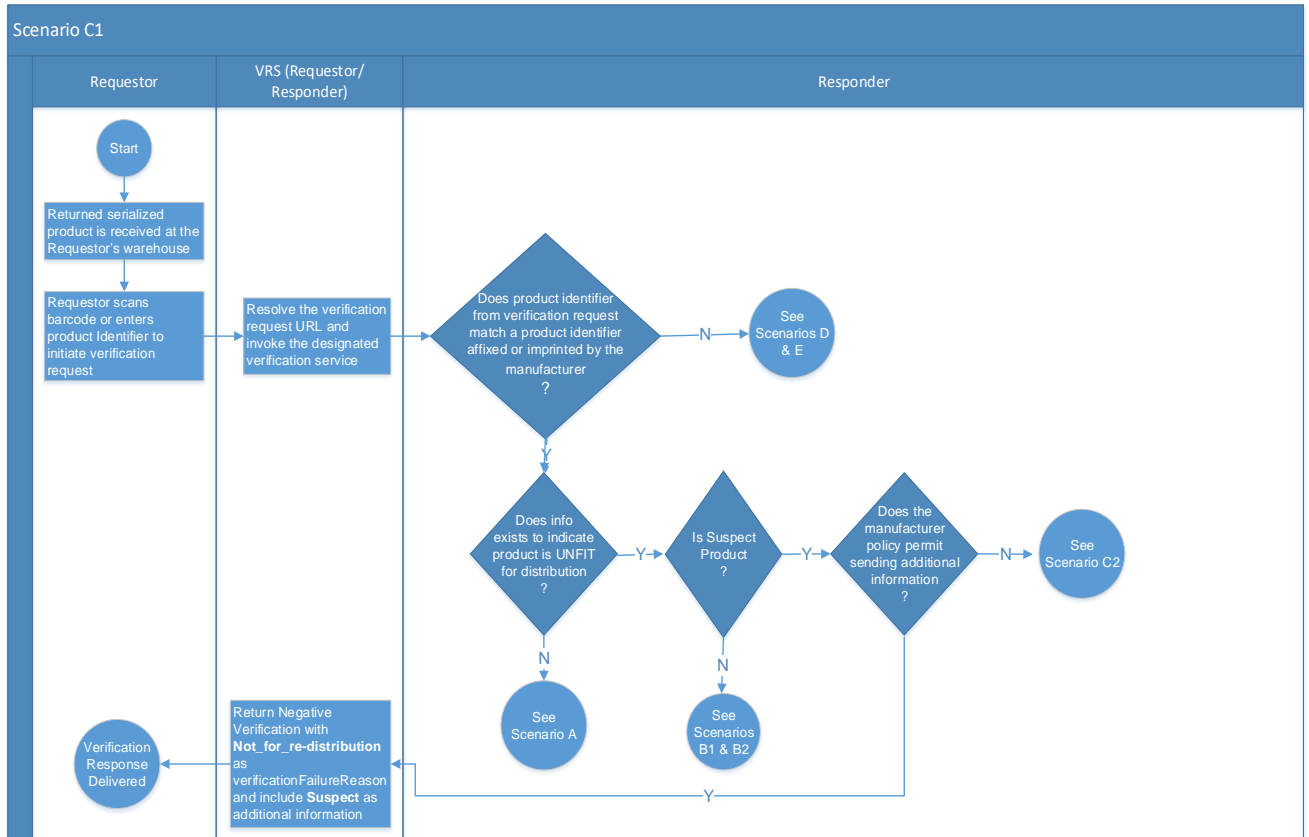


The example below illustrates a sample JSON response to a request for verification of a returned product identifier following failure of verification, which includes `Expired` as additional information. In this example, the Correlation UUID is `21EC2020-3AEA-4069-A2DD-08002B30309D`, and the GLN of the manufacturer responding to the verification request is `0312231245676`.

```
HTTP 1.1 200 OK
Cache-Control: private, no-cache
Content-Type: application/json
{
 "verificationTimestamp": "2018-08-14T23:29:00.000-08:00",
 "responderGLN": "0312231245676",
 "data" : {
 "verified": false,
 "verificationFailureReason": "Manufacturer_policy",
 "additionalInfo": "Expired"
 },
 "corrUUID": "21EC2020-3AEA-4069-A2DD-08002B30309D"
}
```

## 8.7 Scenario C1

In scenario C1, the product identifier matches a value in the responder’s repository, and the responder has reason to believe that the product is suspect. The responder returns a false verification response and provides “Not\_for\_re-distribution” as a reason for the verification failure with “Suspect” as additional information.



The example below illustrates a sample JSON response to a request for verification of a returned product identifier following negative verification, with “Not\_for\_re-distribution” as reason for failure and additionalInfo of "Suspect". In this example, the Correlation UUID is 21EC2020-3AEA-4069-A2DD-08002B30309D, and the GLN of the manufacturer responding to the verification request is 0312231245676.

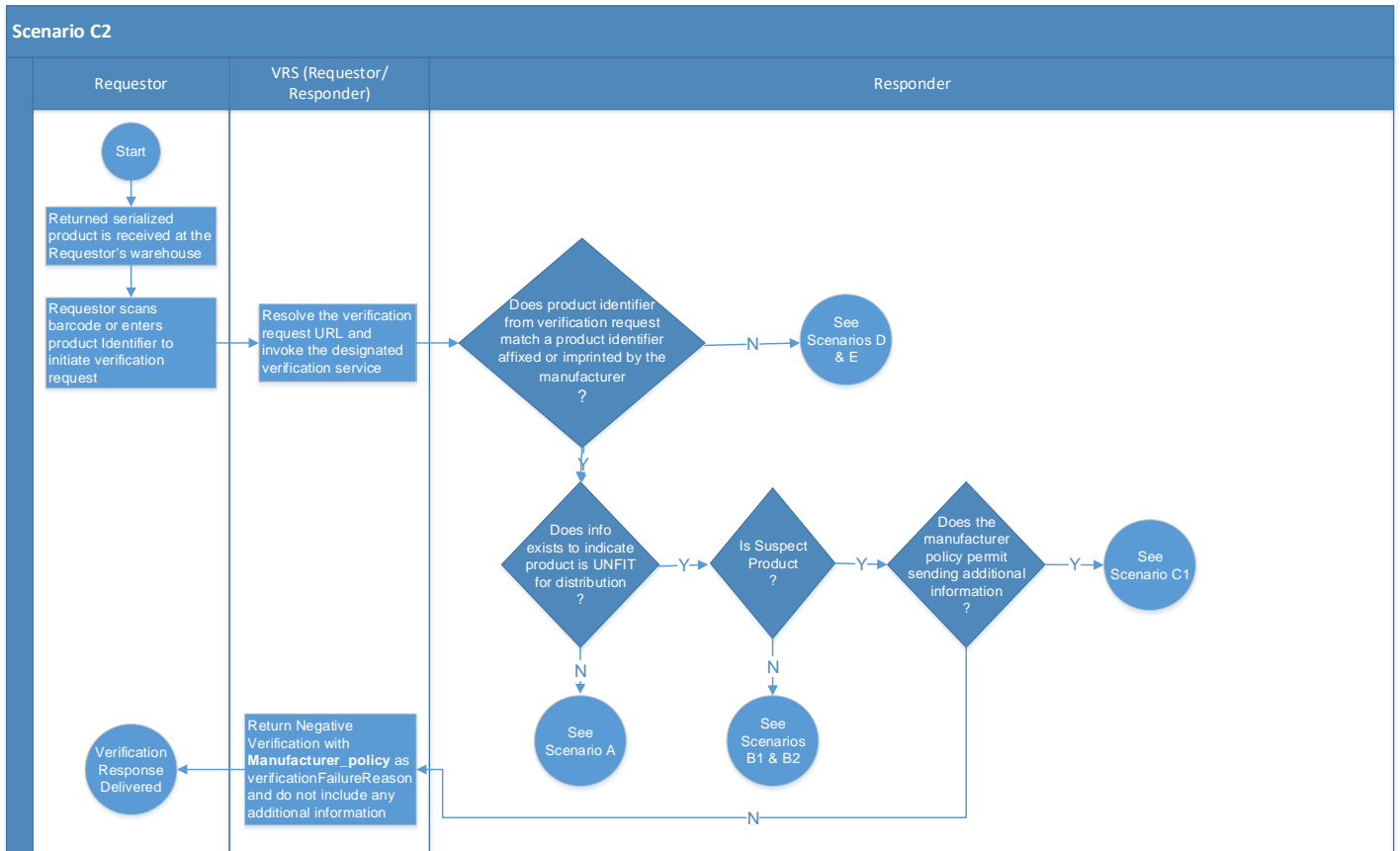
```

HTTP 1.1 200 OK
Cache-Control: private, no-cache
Content-Type: application/json
{
 "verificationTimestamp": "2018-08-14T23:29:00.000-08:00",
 "responderGLN": "0312231245676",
 "data" : {
 "verified": false,
 "verificationFailureReason": "Not_for_re-distribution",
 "additionalInfo": "Suspect"
 },
 "corrUUID": "21EC2020-3AEA-4069-A2DD-08002B30309D"
}

```

## 8.8 Scenario C2

In scenario C2, the product identifier matches a value in the responder’s repository, and the responder has reason to believe that the product is unfit for distribution. Based on the manufacturer’s policy, the responder returns a false verification response and provides “Manufacturer\_policy” as a reason for the verification failure without additional information.



The example below illustrates a sample JSON response to a request for verification of a returned product identifier following negative verification, with “Manufacturer\_policy” as reason for failure without providing any additional information. In this example, the Correlation UUID is 21EC2020-3AEA-4069-A2DD-08002B30309D, and the GLN of the manufacturer responding to the verification request is 0312231245676.

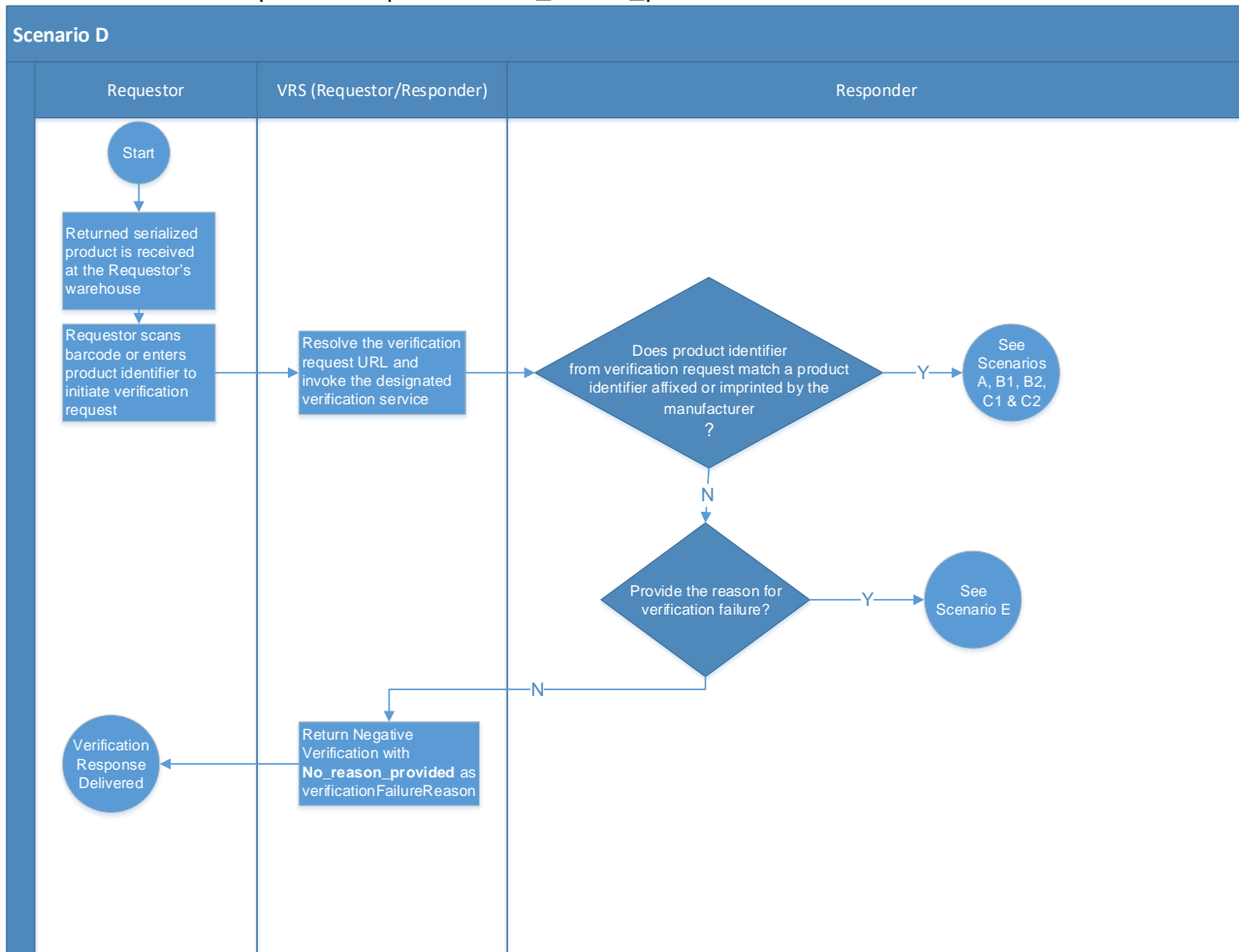
```

HTTP 1.1 200 OK
Cache-Control: private, no-cache
Content-Type: application/json
{
 "verificationTimestamp": "2018-08-14T23:29:00.000-08:00",
 "responderGLN": "0312231245676",
 "data" : {
 "verified": false,
 "verificationFailureReason": "Manufacturer_policy"
 },
 "corrUUID": "21EC2020-3AEA-4069-A2DD-08002B30309D"
}

```

## 8.9 Scenario D

In scenario D, the product identifier does not match a value in the responder's repository. The responder returns a false verification response and provides "No\_reason\_provided" as a reason for the verification failure.

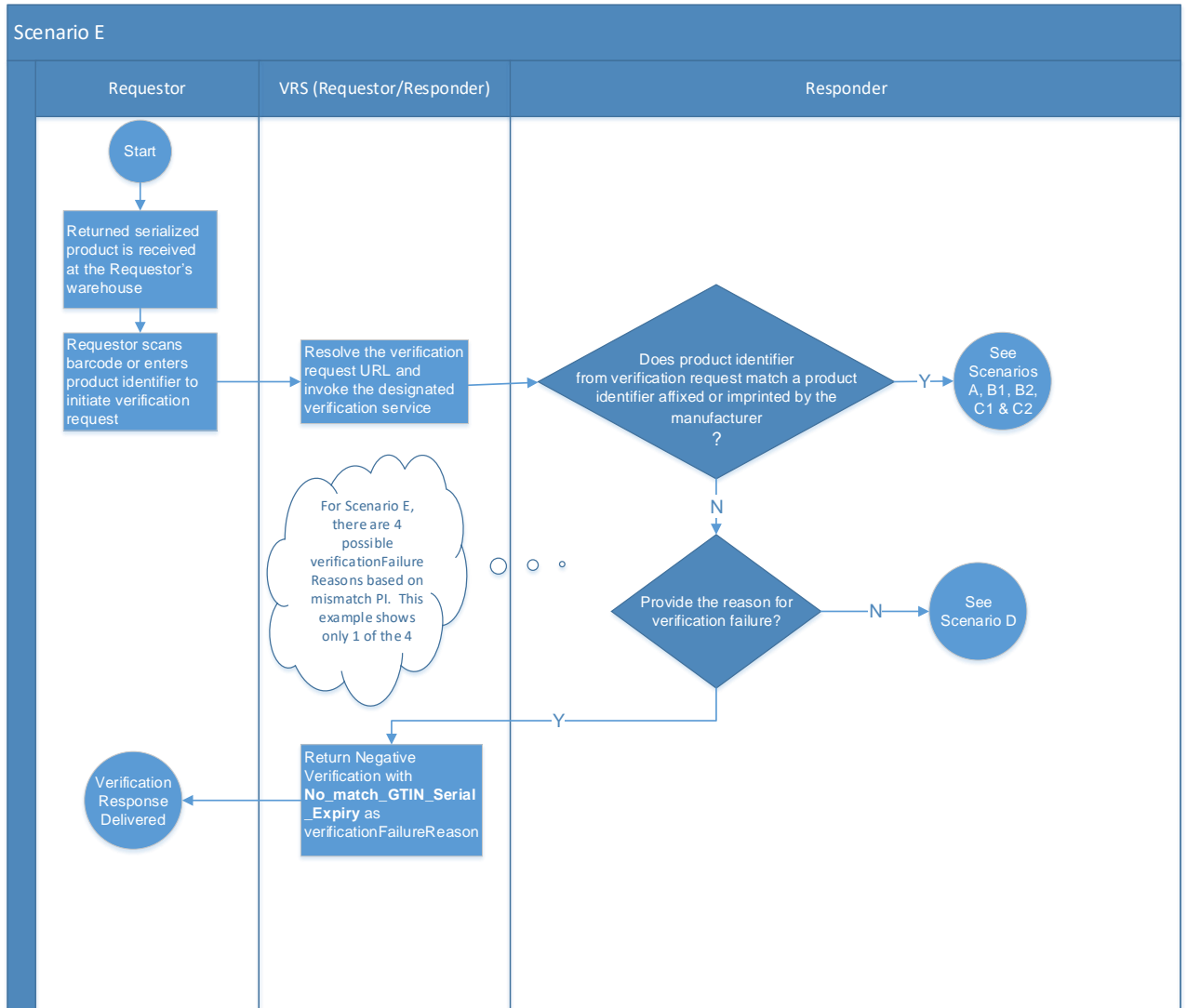


The example below illustrates a sample JSON response to a request for verification of a returned product identifier following failure of verification, with "No\_reason\_provided" as reason for failure. In this example, the Correlation UUID is 21EC2020-3AEA-4069-A2DD-08002B30309D, and the GLN of the manufacturer responding to the verification request is 0312231245676.

```
HTTP 1.1 200 OK
Cache-Control: private, no-cache
Content-Type: application/json
{
 "verificationTimestamp": "2018-08-14T23:29:00.000-08:00",
 "responderGLN": "0312231245676",
 "data": {
 "verified": false,
 "verificationFailureReason": "No_reason_provided"
 },
 "corrUUID": "21EC2020-3AEA-4069-A2DD-08002B30309D"
}
```

## 8.10 Scenario E

In scenario E, the product identifier does not match a value in the responder's repository. Besides "No\_reason\_provided", there are four other possible reasons listed in section 8.2 for the product identifier mismatch: "No\_match\_GTIN\_Serial", "No\_match\_GTIN\_Serial\_Lot\_Expiry", "No\_match\_GTIN\_Serial\_Lot", "No\_match\_GTIN\_Serial\_Expiry". The specific example illustrated in this section shows the responder returning a false verification response and providing "No\_match\_GTIN\_Serial\_Expiry" as a reason for the verification failure.



The example below illustrates a sample JSON response to a request for verification of a returned product identifier following failure of verification, providing "No\_match\_GTIN\_Serial\_Expiry" as failure reason for illustration purposes only. Note that this reason for failure is one of the other 4 possible choices. In this example, the Correlation UUID is 21EC2020-3AEA-4069-A2DD-08002B30309D, and the GLN of the manufacturer responding to the verification request is 0312231245676.

```
HTTP 1.1 200 OK
Cache-Control: private, no-cache
Content-Type: application/json
{
 "verificationTimestamp": "2018-08-14T23:29:00.000-08:00",
 "responderGLN": "0312231245676",
 "data" : {
 "verified": false,
 "verificationFailureReason": "No_match_GTIN_Serial_Expiry"
 },
 "corrUUID": "21EC2020-3AEA-4069-A2DD-08002B30309D"
}
```

## 9 Exception Handling

### 9.1 Potential list of HTTP status code responses returned when processing connectivity or verification requests

Code	Description
200	A response code of 200 means the request was successful and details about the response can be found in the body of the response. Only a 200 response will issue a JSON payload.
400	Bad request. The request was not formatted properly.
401	Unauthorized. The request was not allowed because the request did not pass authentication.
403	Forbidden. The request was valid, but the server is refusing to provide a response because the requestor lacks permission.
404	Not found. GTIN may be missing in Lookup Directory/Resolver.
405	Method not allowed. The request method is not supported.
408	Request timeout. The server timed out waiting for the request.
500	Internal server error. System failed to process the request because of an error inside the system.
502	Bad gateway. The server was acting as a gateway or proxy and received an invalid response from the upstream server. Indicates that one server tried to use another VRS system and that system was down.
503	Service unavailable. System is undergoing maintenance or is otherwise temporarily unavailable for API queries.
504	Gateway timeout. The server, while acting as a gateway or proxy, performed multiple retries but did not receive a timely response from the upstream server specified by the URI (e.g. HTTP, FTP, LDAP) or some other auxiliary server (e.g. DNS) it needed to access in attempting to complete the request.

## 9.2 Potential resolution paths for HTTP status code responses

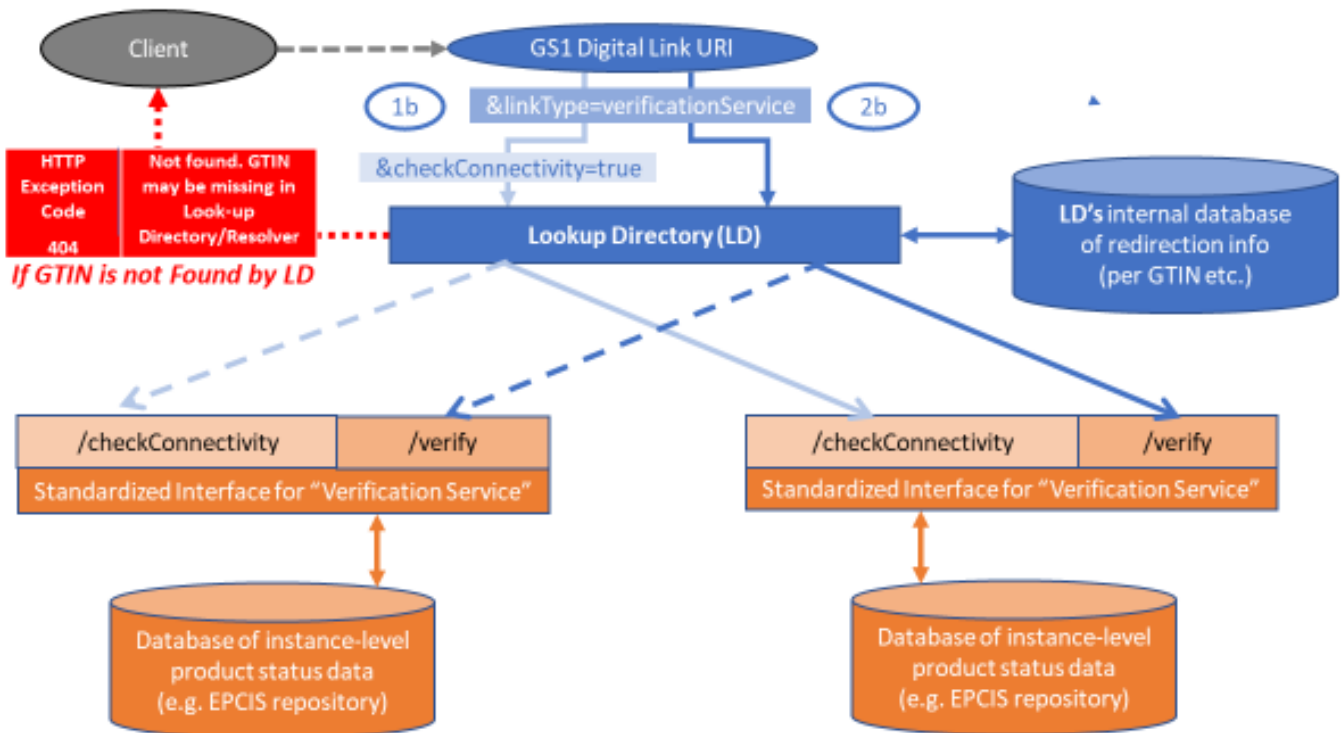
HTTP Status Code	Suggested Resolution
200	None
400	Check that the request conforms to the specification and reissue the request in the correct format.
401	Check and obtain necessary authentication credentials.
403	Check and obtain necessary permission and credentials.
404	Check URI format and correct resource paths and names. Contact Mfg. to confirm the GTIN exists. Contact verification service provider to ensure lookup directory is synchronized.
405	Check and correct method names and parameters.
408	Re-try sending the request to the server. If timeout continues, check connectivity request to server and contact verification service provider.
500	Contact verification service provider.
502	Re-try sending the request to the server. If timeout continues, check connectivity request to server and contact verification service provider.
503	Re-try sending the request to the server. If timeout continues, check connectivity request to server and contact verification service provider.
504	Re-try sending the request to the server. If timeout continues, check connectivity request to server and contact verification service provider.

## 9.3 Exception handling example for GTIN not found

While it is expected for GTINs to be registered in a lookup directory (LD), it is possible, though unlikely, for the GTIN information to be missing from an LD. In the figure 9-1 below, we are describing an example of an exception handling process when the GTIN is not found in the LD. Although the GS1 Digital Link URI is syntactically valid, the LD has no information about the GTIN contained in the URI. Since there is no GTIN record in the LD, the verification request cannot be routed to any verification service. The verification request never makes it past the LD. Consequently, the response returned can neither be a positive, nor negative verification response. Hence, the LD returns an HTTP status code of 404: Not Found. GTIN may be missing in lookup directory/resolver.



**Figure 9-1** an example of an exception handling process when the GTIN is not found in the lookup directory.



As shown in section 9.2, suggested resolution steps for a 404 HTTP status code response include:

- Checking URI format and correcting resource path and names
- Contacting manufacturer to confirm the GTIN exists
- Contacting your verification service provider to ensure the LD is synchronized

## 10 Abbreviations and Terms

Abbreviation	Term
context	Parameter within each verification request which serves as a reference to a bundle of input parameters for the product identifier and selected master data attributes, as well as an interpretation (or reference to an interpretation) of the true/false response; for example, "dscsaSaleableReturn" indicates a verification application within the US DSCSA's provision for Verification of Saleable Returns.
DSCSA	Drug Supply Chain Security Act, comprising Title II of the DQSA, outlines steps to build an electronic, interoperable system to identify and trace certain prescription drugs as they are distributed in the United States
EPCIS	Electronic Product Code Information Services, a GS1 and ISO Standard that defines a common data model for visibility data and interfaces for capturing and sharing visibility data within an enterprise and across an open supply chain
FDA	Food and Drug Administration, a federal agency of the United States Department of Health and Human Services
GLN	Global Location Number, a GS1 identification key used to identify physical locations or parties. The key comprises a GS1 Company Prefix, location reference, and check digit
GTIN	Global Trade Item Number, a GS1 identification key used to identify trade items. The key comprises a GS1 Company Prefix, an item reference and check digit
HDA	Healthcare Distribution Alliance, the US national organization representing primary pharmaceutical distributors
HTTP	Hypertext Transfer Protocol, an application protocol for distributed, collaborative, hypermedia information systems
HTTPS	Hypertext Transfer Protocol Secure, an extension of the Hypertext Transfer Protocol (HTTP) for secure communication over a computer network, widely used on the Internet
JSON	JavaScript Object Notation, an open-standard file format that uses human-readable text to transmit data objects consisting of attribute-value pairs and array data types
JSON-LD	JavaScript Object Notation for Linked Data, a method of encoding Linked Data using JSON.
linkType	Specification of the nature of the information being linked to, to request a specific type of information or service; for example, "verificationService".
Requestor	Party that submits a verification request; for example, in the context of "dscsaSaleableReturn", a pharmaceutical wholesale distributor.
Responder	Party that responds to a verification request; for example, in the context of "dscsaSaleableReturn", a pharmaceutical manufacturer or repackager.
REST	Representational State Transfer, an architectural style that defines a set of constraints to be used for creating web services
SNI	Standardized Numerical Identifier, defined by the DSCSA as "a set of numbers or characters used to uniquely identify each package or homogenous case that is composed of the National Drug Code that corresponds to the specific product (including the particular package configuration) combined with a unique alphanumeric serial number of up to 20 characters."
URI	Uniform Resource Identifier, a string of characters that unambiguously identifies a particular resource
UUID	Universally Unique Identifier, a practically unique, 128-bit number used to identify information in computer systems

VRS	Verification Router Service, potential method to meet the 2019 Saleable Returns DSCSA Requirements, designed to reference a returned pharmaceutical product's GTIN or associated GCP to automatically query the appropriate manufacturer's database and return a response in real-time
-----	----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

## 11 Appendix

### 11.1 OpenAPI Schema (including JSON) for U.S. Verification Request & Response Requirements

You may [access and download the OpenAPI Schema](#) from GS1 US.

```

{
 "openapi": "3.0.0",
 "info": {
 "version": "1.0.0",
 "title": "GS1 Verification Messaging Standard",
 "contact": {
 "name": "GS1",
 "url": "https://www.gs1.org",
 "email": "gsmp@gs1.org"
 },
 "description": "This the API specification for peer-to-peer communication between Verification Router Services or VRS"
 },
 "servers": [
 {
 "url": "https://vrs.example.com/gateway/placeholder"
 }
],
 "paths": {
 "/checkConnectivity": {
 "get": {
 "tags": [
 "Test"
],
 "description": "Test connection to endpoints",
 "parameters": [
 {
 "name": "gtin",
 "in": "query",
 "description": "Global Trade Item Number",
 "required": true,
 "schema": {
 "$ref": "#/components/schemas/gtin"
 }
 },
 {
 "name": "reqGLN",
 "in": "query",
 "description": "Requestor GLN",
 "required": true,
 "schema": {

```

```

 "$ref": "#/components/schemas/gln"
 }
},
{
 "name": "linkType",
 "in": "query",
 "description": "Link Type",
 "required": true,
 "schema": {
 "$ref": "#/components/schemas/linkType"
 }
},
{
 "name": "context",
 "in": "query",
 "description": "Verification Context",
 "required": true,
 "schema": {
 "$ref": "#/components/schemas/context"
 }
}
],
"responses": {
 "200": {
 "description": "A response code of 200 means the request was successful and details about the response can be found in the body of the response. Only a 200 response will issue a JSON payload.",
 "content": {
 "application/json": {
 "schema": {
 "$ref": "#/components/schemas/ConnectivityCheckResponse"
 }
 }
 }
 },
 "400": {
 "description": "Bad Request. The request was not formatted properly. Please verify the request conforms to the specification, and re-issue the request in the correct format."
 },
 "401": {
 "description": "Unauthorized. The request was not allowed because the request did not pass authentication."
 },
 "403": {
 "description": "Forbidden. The request was valid, but the server is refusing to provide a response because the requestor lacks permission."
 },
 "404": {
 "description": "Not found. GTIN may be missing in Lookup Directory/Resolver."
 },
 "405": {
 "description": "Method Not Allowed. The request method is not supported."
 },
 "408": {
 "description": "Request Timeout. The server timed out waiting for the request."
 }
}

```

```

 "500": {
 "description": "Internal Server Error. System failed to process the request because of an error inside the
system."
 },
 "502": {
 "description": "Bad Gateway. The server was acting as a gateway or proxy and received an invalid response
from the upstream server. Indicates that one server tried to use another VRS system and that system was down."
 },
 "503": {
 "description": "Service Unavailable. System is undergoing maintenance or is otherwise temporarily
unavailable for API queries."
 },
 "504": {
 "description": "Gateway Timeout. The server, while acting as a gateway or proxy, performed multiple retries
but did not receive a timely response from the upstream server specified by the URI (e.g. HTTP, FTP, LDAP) or
some other auxiliary server (e.g. DNS) it needed to access in attempting to complete the request."
 }
 }
},
"/verify/gtin/{gtin}/lot/{lot}/ser/{ser}": {
 "get": {
 "tags": [
 "Verification"
],
 "description": "Verify a saleable return",
 "parameters": [
 {
 "name": "gtin",
 "in": "path",
 "description": "Global Trade Item Number",
 "required": true,
 "schema": {
 "$ref": "#/components/schemas/gtin"
 }
 },
 {
 "name": "lot",
 "in": "path",
 "description": "Lot/Batch Number",
 "required": true,
 "schema": {
 "$ref": "#/components/schemas/lotNum"
 }
 },
 {
 "name": "ser",
 "in": "path",
 "description": "Serial Number",
 "required": true,
 "schema": {
 "$ref": "#/components/schemas/serialNumber"
 }
 }
]
 }
},

```

```

{
 "name": "exp",
 "in": "query",
 "description": "Expiry",
 "required": true,
 "schema": {
 "$ref": "#/components/schemas/expiryDate"
 }
},
{
 "name": "linkType",
 "in": "query",
 "description": "Link Type",
 "required": true,
 "schema": {
 "$ref": "#/components/schemas/linkType"
 }
},
{
 "name": "context",
 "in": "query",
 "description": "Verification Context",
 "required": true,
 "schema": {
 "$ref": "#/components/schemas/context"
 }
},
{
 "name": "reqGLN",
 "in": "query",
 "description": "Requestor GLN",
 "required": true,
 "schema": {
 "$ref": "#/components/schemas/gln"
 }
},
{
 "name": "corrUUID",
 "in": "query",
 "description": "Correlation UUID",
 "required": true,
 "schema": {
 "$ref": "#/components/schemas/uuid"
 }
}
],
"responses": {
 "200": {
 "description": "A response code of 200 means the request was successful and details about the response can be found in the body of the response. Only a 200 response will issue a JSON payload.",
 "content": {
 "application/json": {
 "schema": {
 "oneOf": [

```

```

 {
 "$ref": "#/components/schemas/PositiveVerificationResponse"
 },
 {
 "$ref": "#/components/schemas/NegativeVerificationResponse"
 }
]
}
},
"components": {
 "schemas": {
 "gln": {
 "type": "string",
 "minLength": 13,
 "maxLength": 13,
 "example": "9071404000002",
 "pattern": "\\d{13}$"
 },
 "gtin": {
 "type": "string",
 "minLength": 8,
 "maxLength": 14,
 "example": "175304202",
 "pattern": "\\d{12,14}\\d{8}$"
 },
 "lotNum": {
 "type": "string",
 "description": "Lot number for the asset to be verified",
 "example": "LZ109B15"
 },
 "serialNumber": {
 "type": "string",
 "description": "Serial number for the asset to be verified",
 "example": "XYZ12345AB"
 },
 "expiryDate": {
 "type": "string",
 "description": "Date of expiry for the item to be looked up in format YYMMDD",
 "minLength": 6,
 "maxLength": 6,
 "example": "230728",
 "pattern": "\\d{6}$"
 },
 "uuid": {
 "type": "string",
 "description": "Universally Unique Identifier (UUID)",
 "example": "59bc5c88-15f7-49a7-9687-73b05d2c50a4",
 "pattern": "^([a-fA-F\\d]{8}-[a-fA-F\\d]{4}-4[a-fA-F\\d]{3}-[89abAB][a-fA-F\\d]{3}-[a-fA-F\\d]{12})$"
 }
 }
}

```

```

 },
 "timestamp": {
 "type": "string",
 "description": "A timestamp to millisecond precision, with an explicit timezone indicator (+/-hh:mm) relative to
UTC",
 "example": "2018-08-14T23:29:00.000-08:00",
 "pattern": "^([0-9]{4})-(0[1-9]|1[0-2])-(0[1-9]|1[0-9]|2[0-9]|3[0-1])T(2[0-3]|[01][0-9]):[0-5][0-9]:[0-5][0-9]\\.([0-9]{3}|Z|((\\+|\\-)((0[0-9]|1[0-3]):([0-5][0-9]))14:00))"
 },
 "linkType": {
 "type": "string",
 "enum": [
 "verificationService"
],
 "example": "verificationService"
 },
 "context": {
 "type": "string",
 "enum": [
 "dscsaSaleableReturn"
],
 "example": "dscsaSaleableReturn"
 },
 "positiveVerificationStatus": {
 "type": "boolean",
 "description": "Please refer to the rules defined for the context for further details of what constitutes successful
verification. If verification succeeds, use true.",
 "example": true,
 "enum": [
 true
]
 },
 "negativeVerificationStatus": {
 "type": "boolean",
 "description": "Please refer to the rules defined for the context for further details of what constitutes
unsuccessful verification. If verification fails, use false and select a value for 'verificationFailureReason'.",
 "example": false,
 "enum": [
 false
]
 },
 "verificationFailureReason": {
 "type": "string",
 "description": "Mandatory if verification failed. Used to indicate which PI element(s) did not match, or to indicate
that no reason has been provided (at the discretion of the responder. Values: 'Manufacturer_policy': 'Pharmaceutical
manufacturers may have different internal policies, which will return a Verified true, or false for the same conditions
or determines whether to return additional information with the verification response.', 'No_match_GTIN_Serial': 'No
match between GTIN and Serial Number', 'No_match_GTIN_Serial_Lot': 'No match between (GTIN and Serial
Number) and Lot Number', 'No_match_GTIN_Serial_Expiry': 'No match between (GTIN and Serial Number) and
Expiry Date', 'No_match_GTIN_Serial_Lot_Expiry': 'No match between (GTIN and Serial Number) and Lot Number
and Expiry Date', 'No_reason_provided', 'Not_for_re-distribution': 'The pharmaceutical manufacturer notifies the
Requestor that the product is Suspect and Not for re-distribution",
 "enum": [
 "Manufacturer_policy",

```



```
"No_match_GTIN_Serial",
"No_match_GTIN_Serial_Lot",
"No_match_GTIN_Serial_Expiry",
"No_match_GTIN_Serial_Lot_Expiry",
"No_reason_provided",
"Not_for_re-distribution"
],
"example": "No_match_GTIN_Serial_Lot"
```

```
},
"additionalInformation": {
 "type": "string",
```

"description": "Optional. May be used to provide additional information of the state of the SGTIN, for example, recalled. Instead of including an empty string or null, do NOT include this field unless is populated with a descriptive, standardised text value. Values: 'Expired' - The product has an expiration date which is in the past; 'Recalled' – Product has been recalled or withdrawn; 'Suspect' - The product's authenticity or integrity is considered suspect by the responder. THIS IS NOT A FREE TEXT DESCRIPTION. Additional values will be standardised in the future. NOTE THAT EPCIS IS THE PREFERRED MECHANISM FOR INDICATING CHANGES IN PRODUCT DISPOSITION (e.g., recalled, stolen, decommissioned).",

```
 "enum": [
 "Expired",
 "Recalled",
 "Suspect"
]
},
```

```
"ConnectivityCheckResponse": {
 "required": [
 "responderGLN"
],
 "properties": {
 "responderGLN": {
 "$ref": "#/components/schemas/gln"
 }
 }
},
```

```
"PositiveVerificationResponse": {
 "required": [
 "verificationTimestamp",
 "corrUUID",
 "responderGLN",
 "data"
],
 "properties": {
 "verificationTimestamp": {
 "$ref": "#/components/schemas/timestamp"
 },
 "corrUUID": {
 "$ref": "#/components/schemas/uuid"
 },
 "responderGLN": {
 "$ref": "#/components/schemas/gln"
 },
 "data": {
 "type": "object",
 "properties": {
```





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## IAPMO

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\*If applicable

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