



DSCSA Quick Update for 2019 **THIS DOCUMENT IS OUR QUICK UPDATE OF WHAT'S NEW FOR 2019**

Updates for 2019

2019 Brings with its Serialization Updates and Mandates The current enforcement date is November 2019

This is a basic overview of how to handle serial numbers today in the MDS System.

1. Prior to shipments coming in – we would expect trading partners (vendor/mfg.) to send in an EDI 856 doc with serials for each lot number , MDS will parse the EDI and during receipts you would Choose the “pending” pedigree info to attach to your receipts -much like we do for lots today.
2. Receiving would then open a percentage of boxes (optional QC and audit task created separately) to audit the receipt and verify the serials. Using Manual verification is just physically checking Items as they come in and making sure they match up to the EDI information.

Note as mentioned we don't see them sending this information, and not all manufacturers/vendors are setup via EDI as well. EPCIS data is supposed to be sent and MDS-Nx is prepared to parse and accept this data , but like an EDI file it will require some mapping and discussion, as some manufacturers will send you just the serials they shipped but many send you all the serials for the production run so that you can do your own verification of saleable returns.

In the event the EDI is not available, or the serials are not available via EDI, we have a new screen at receiving/button to allow you to train/create barcodes by Vendor

In the GS1 barcode screen we have added a new field for ScanID – if you are on the Scan Id field – we will parse the scanned barcode for

Identifiers - <https://www.gs1.org/standards/barcodes/application-identifiers?lang=en>

Key ones are

01	Global Trade Item Number	n2+n14	GTIN
10	Batch or lot number	n2+an..20	BATCH/LOT
17	Expiration date (YYMMDD)	n2+n6	USE BY OR EXPIRY
21	Serial number	n2+an..20	SERIAL
240	Additional product identification assigned by the manufacturer	n3+an..30	ADDITIONAL ID

Each vendor may have different layouts for the data and or include different identifiers, the scanner you use will often add their own delimiters as well.

Because of this we need to know the scanners and what the delimiter used for your scanner is.



To make things simpler we are recommending you purchase Scan Avenger 3-in-1 Hand Scanners - Cordless, Rechargeable 1D and 2D Scan Gun for Inventory Management

Below is a and Example GS1 Data Matrix barcode.



ScanAvenger Portable
Wireless Bluetooth Barcode
Scanner: 3-in-1 Hand
Scanners - Cordless,...

★★★★☆ ~ 154

\$58⁹⁷

This barcode contains 4 fields:

GTIN, or global trade identification number ,Lot or Batch number, Expiration Date, Serial Number One scan of this barcode returns all four fields which we then parse into 4 separate fields. The lot and serial number fields are variable in length. Variable length fields that fall within the middle of the barcode are appended with a group separator character. The Model Scanner Above Scan Avenger – can found on Amazon for under \$60.

The original model we tested was # AS8862

https://www.amazon.com/gp/product/B07N8MG38F/ref=ppx_yo_dt_b_search_asin_title?ie=UTF8&psc=1

Out of the box this model will scan GS1 Data Matrix barcodes and provide the group separator character within the data.

Amazon is now shipping the new model # AS8880 , this model will scan GS1 Data Matrix barcodes but will **NOT** provide the group separator character. The scanner must be programmed by scanning the two images below.



The Systems House, Inc.

Notch View Office Park
1033 Route 46
Clifton, NJ 07013

Tel. (973) 777- 8050
Fax (973) 777- 3063

Scan image #1 then image #2.

Image 1



Image 2



Check the model number before you have the customer program the scanner. The model number can be found on a label next to the trigger.



Saleable returns requirement

Much like you must do today, you are supposed to verify any product that is returned prior to selling it again. What has changed is that you now need to do this down to the serial number level, whereas before the lot number on the pedigree document (t3 info) and the pedigree itself were enough to verify this item was the one you sold.

One solution being offered is a VRS - Verification Router Service.

Below is a quick overview of how a VRS will work, it does not in any way require you to connect directly as most partners will have a web portal as well

The manufacturers in theory must provide the information. However, should you wish to connect directly to the VRS so you do not have to retype or scan your serial numbers you can do so.

This would be treated like any other EDI transaction even if the format is slightly different. And is typically real time.

More info here MDS-Nx supports the lightweight message standard for real time verification of the products. However currently (September 2019) – The responses are not standardized so you may need to review still manually what the status returned really means.

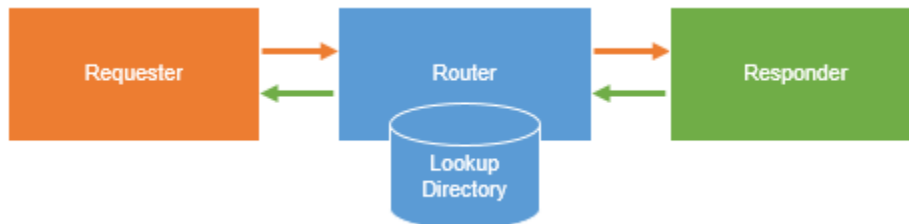
https://www.gs1.org/docs/standards/gs1_lightweight_verification_messaging_standard_v_1_0_2.pdf

The current best practice is to use the web portal to scan in your barcodes and verify them. Again, as VRS becomes more mainstream we will likely add them as EDI partners and Integrate the different providers, much like we do for EDI 856 documents today (electronic t3 info)



A Verification Router Service connects manufacturers and wholesalers

each one has a separate setup, and it would be a new EDI transaction for the verification etc.



The VRS model provides three basic service components:

Wholesalers use the requester service to create and submit a verification request and receive the response.

The router service uses its lookup directory to locate the product information and route the request to the correct source.

Manufacturers use the responder service to receive the verification request and respond to the requester.

Verification of Product Identifiers for pharmaceuticals Under the Drug Supply Chain Security Act (DSCSA) § 582(c)(4)(D), beginning November 27, 2019,

wholesaler distributors are required to verify the product identifier including Standardized Numerical 149 Identifier (SNI) of products returned to them before the returned products can be placed into inventory for resale. DSCSA defines verification as the process of “determining whether the product identifier affixed to or imprinted upon a package or homogeneous case corresponds to the [SNI] ... assigned to the product by the manufacturer or the repackager....” [§ 581(28)]

“Verification” or “verify” means “determining whether the product identifier affixed to or imprinted upon on a package or homogeneous case corresponds to the [SNI] ... assigned to the product by the manufacturer or the repackager....” [§ 581(28)]. A manufacturer who receives a verification request 156 from a repackager, wholesale distributor, or dispenser must respond to that request within 24 hours (or such other time the Food and Drug Administration (FDA) establishes) [§ 582(b)(4)(C)]. A repackager also has 24 hours to respond [§ 582(e)(4)(C)].



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For MDS-Nx Clients to simplify a vrs is just an electronic way of verifying the serial numbers are real.

Technically as part of dcscs - when you get a product in currently you are supposed to get a t3 doc (pedigree) - with the lot# on it. you are then supposed to verify the product is real with the manufacturer who is listed on the document. in november of this year (2019) they added the serial number to requirement, so you now must verify the serial number.

For Saleable Returns they have also required that all the items you get back as returned from your pharmacy/customers are verified.

Since you sold them - MDS would not allow you to take the return normally if the lot# does not match. And when you resell it - you can decide if you want to show the customer it was touched by another pharmacy who could have potentially swapped it for an older or different product. The T3 (pedigree) doc in MDS has the information you can choose what parameters you want and decide if this information shows to the next customer in your supply chain.

Having said that the VRS is not part of the law - it is just designed to make it easier and of course it will likely cost money on both sides. Most of the times much like the t3 info - the manufacturer picks up the cost and you just get the info delivered to you.

As a reminder if you do not have the latest updates you will likely not have all these features so please make sure to update your MDS system as soon as possible to remain in compliance.