



Product Release to EU Countries

Previously distributed to EC on December 29, 2020

December 24, 2020

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Overall Manufacturing and release process

DS Manufacturing + Testing Lonza Visp (Switzerland)	DP Manufacturing + Testing Rovi (Spain)	OMCL testing at AGES laboratory (Austria)	Shipment to Centralized Warehouse (Belgium)	Shipment to local country	
DS release done by the lonza site	done by the ma Rovi (Spain) and	e and EU certification inufacturing site QP in including the CoA from atory as a pre-requisite	by the Mo release	Release process. release the batch taken oderna RP based on documents from ng sites and shipment	

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General Process overview

- The product will have a technical release and EU batch certification from the manufacturing site QP and must be in released/approved status in the European distribution center before shipment to the destination country.
- Product is shipped to a distribution warehouse defined by the customer in the destination country under the following arrangement:

DAP/DDP - Moderna is responsible for shipment to a designated storage and distribution center or transit point in the destination country. In such cases, Moderna is part of the final in-country release process together with the customer or their agent.

 Status control on receipt at the in-country distribution warehouse will be the responsibility of the customer or their agent. The **Moderna release process** is based on review of the relevant documentation for the batch. This includes, but is not limited to:

- Release documentation from the manufacturing sites, including Certificate of Analysis and Certificate of Conformance (also termed Certificate of Manufacturing in some jurisdictions) for Drug Substance and Drug Product.
- Shipping documentation: packing lists, security seal records, etc.
- Shipping controls, e.g., temperature records, including datalogger placement and readouts.
- Receiving record at the destination warehouse.

The Moderna RP carries out a review of the documentation listed above, following arrival at the destination warehouse.

The Moderna RP will decide on the release or withholding of the product. The decision on the status of the product will be communicated to the destination warehouse.

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Shipment, in-country receipt, and release of product

Shipment to in-country distribution centers

- Modema Supply Chain will advise the customer or their agent that the material is available for delivery.
- The European distribution warehouse will arrange the transport of the material, including:
 - preparation of packing lists,
 - truck/container preconditioning,
 - datalogger placement, truck/container seals, etc.
 - The records of these actions will be sent to Moderna QA
- Moderna Supply Chain will advise the customer or their agent of the intended delivery date and time. The European distribution center will execute the shipment as directed by Moderna Supply Chain.
- The European distribution center will send confirmation of shipment to the RP at Moderna Switzerland. This will include copies of packing lists and shipping documents as outlined above.

Receipt of product at the in-country distributor

- The in-country distributor will carry out incoming checks for the labeled identity (product name, batch number, quantity) of the material as well as seal checks.
- The distributor will also retrieve dataloggers or other temperature recording devices from the shipment. The analysis of the temperature data will typically be done by the distributor and the results sent to Moderna QA in Basel.
- The distributor should also confirm that the goods have been received in good physical condition. Any discrepancy in the incoming checks at the distributor should be notified to Moderna QA in Basel within 24 hours of goods receipt.
- The distributor will collect and store the retention samples for each batch in accordance with European and/or local national requirements.

Release of product by Moderna

- The RP at Moderna QA will review the documentation provided by the manufacturing site, the European distribution warehouse, and the in-country distributor.
- If the RP is satisfied that the product is of suitable quality, and that the manufacturing, transportation and warehousing records confirm compliance with GMP/GDP, they may release the product.
- This release will be recorded and batch status changed in SAP accordingly.
- The confirmation of release will be sent to the distributor.
- Further controls within distribution operations will be managed by the distributor.

1. DAP/DDP where Moderna is responsible for shipments



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International Logistics Information

January 4, 2021

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Packaging Configuration



	Vial	Pack	Shipping Case	Pallet
Vials/Doses	1 Vial 10 doses	1 Pack 10 Vials 100 Doses	1 Shipping Case 12 Packs 120 Vials 1,200 Doses	1 Pallet 96 Shipping Cases 1,152 Packs 11,520 Vials 11,5200 Doses
Dimensions & weights	H: 50mm D: 24mm	H: 60mm L: 51mm W: 126mm 217g	H: 135mm L: 267mm W: 169mm 2.7kg	H: 960mm L: 1,200mm W: 800mm 290kg
Packaging features	Tamper evident Vial cap	Tamper evident label on Pack		
GTIN	00380777700687	30380777700688	50380777700682	N/A
Label	LOT & EXP - Printed Only (No Barcode) QR Code encoded with: https://www.ModernaCovid 19Global.com	Product Code, EXP & LOT - Printed & 2D Data Matrix (Not serialized) QR Code encoded with: https://www.ModernaCovid 19Global.com	Product Code, EXP & LOT - Printed & 1D GS1-128 (Not serialized)	Serial Shipping Container Code (SSCC) Label
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Transport, Handling and Storage

- All vaccines shipped out of Central Warehouse at Kuehne & Nagel in Belgium
- -20°C (-25°C to -15°C) for storage and transport
 - No dry ice allowed
- Maximum handling time in 2°C to 8°C
 - 30min for loading and unloading
- · Sensitech loggers added to the product for temperature control
 - Low Temp / High Temp: -25°C to -15°C
 - Interval: Every 5 minutes
 - Start-up delay: 0 minutes
- Transport Equipment
 - Transport in -25°C to -15°C pharma trucks / trailers (Qualified Active System)

- Transport in va-Q-Tec containers (Qualified Passive System)
- No X-Ray allowed

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Transport Concept

Road

- Truck / Trailer with active temperature control -25°C to -15°C
- Van with passive va-Q-Tec system in 2°C to 8°C
 - Quantities up to 2 pallets
 - Containers to be unloaded and returned with delivery van
- GPS tracked (temperature and position)
- · Security concept escort service door-to-door

Air

- Passive va-Q-Tainer system shipping in 2°C to 8°C
 - Containers to be unloaded and returned (to va-Q-Tec depot)
- GPS tracked
- · Security concept escort service for pre- and onward carriage

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Transport Equipment Trailers

Qualified Active System for road transports

- Qualified according to the GDP standards
- FRC certified and qualified
- Equipped with Bi-temperature and Double-deck equipment + ADR
- Equipped with Idem Telematic system with Full visibility and Alarm setting
- TAPA compliant trailers, equipped with high security locks
- -25°C to -15°C



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Transport Equipment va-Q-Tec

Qualified Passive System for Air transport and Road / Van solution

- va-Q-one
 - Qualified, dry-ice free single-use thermal packaging solution
 - >96h according to ISTA 7D (summer & winter profile)
- va-Q-proof
 - Qualified, dry-ice free reusable thermal packaging solution
 - from >96h to >168h according to ISTA 7D (summer & winter profile)
 - box portfolio from 4 to 264 L payload volume
- va-Q-pal
 - Qualified, dry-ice free pallet shipper
 - >95h according to ISTA 7D (summer & winter profile)
 - re-qualification with va-Q-check® possible for re-use
- va-Q-tainer
 - deviation-free, adv anced passive container ≥ 102 hrs
 - 4 different sizes (EUROx, TWINx, Usx, XLx)
 - Global shipments and pay-per-use-rental

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Vaccines Transport Warehouse to customer

Requirement	Description
Shipping temperature	-20°C (-25°C to -15°C) / No dry ice allowed
Packaging configuration	Shipping Cases Pallets
Shipping System	Qualified Active System (Vehicle) Qualified Passive System (PCM)
Load	Depends on customer order (shipping cases, picked pallets, full pallets)
Transport Mode	Road / Air
Temperature Monitoring Strategy	100% monitoring of shipment
Routes / Duration	K+N, Liege/Brussels BE – Worldwide Distribution
Chain of Custody	Tamper resistant seal Dedicated fleet of trucks Door to Door / Nonstop Temperature monitoring & recording and GPS technology while in transport



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