2.3.R Regional Information

The PFS (Pre-Filled Syringe) is a single-dose, single-entity drug/device combination product. It is intended for manual intramuscular injection of 0.5 mL or 0.25 mL of the mRNA-1273 (0.1 mg/mL) vaccine by HCPs (Healthcare Professionals). The PFS is the container closure for the sterile drug product. The container closure system is composed of the following components: syringe barrel, plunger, plunger rod, and rigid tip cap.

As per EU Medical Device Regulation 2017/745 Article 117, the mRNA-1273 PFS is classified as a single entity (i.e., integral), non-reusable combination product containing a medicinal product that has the primary mode of action. Thus, as per MDR 2017/745 Article 117, Moderna has obtained a Notified Body opinion (EXT-13935) from Det Norkse Veritas (DNV) Product Assurance AS (Norway) demonstrating conformance to MDR 2017/745 Annex 1 General Safety and Performance Requirements (GSPR) for the drug delivery system (i.e., PFS), as part of the medicinal product marketing application.

This document cannot be used to support any marketing authorisation application and any extensions or variations thereof
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