Title: QA Certificate

janssen | PHARMACEUTICAL COMPANIES OF Johnson&Johnson

QA CERTIFICATE

SITE OF MANUFACTURING:	**Janssen Pharmaceuticals** 1000 U.S. Route 202 South, Raritan, NJ, USA 08869
PRODUCT NAME:	**CARVYKTI** (ciltacabtagene autoleucel) Dispersion or Suspension, for Intravenous Infusion only
STATEMENT OF ACTIVE SUBSTANCE:	Autologous human T cells genetically modified *ex vivo* using a lentiviral vector encoding an anti-BCMA chimeric antigen receptor (CAR).

PATIENT INFORMATION	
Patient Name	
Patient DOB	
SEC / DIN	
Order ID	
Patient weight (Kg)	Kg

BATCH INFORMATION			
Batch/Lot Number	**COI Bag ID**	**Total Volume (mL) per Bag**	**Product Dose per Bag**
		mL	

Expiration Date	
Package Size and Type	One sterile bag for Infusion and one metal cassette containing one individually packed Infusion bag.
Product NDC	
PCC Number	

MARKETING AUTHORIZATION HOLDER	
Name and Address	
Marketing Authorization Number	
Country	

SPECIAL STORAGE CONDITION

Store and transport frozen (≤ -120 °C). Keep infusion bag in the metal cassette until ready for thaw and administration. Once thawed do not shake, refrigerate or re-freeze

SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

This medicine contains genetically modified cells. Unused medicine or waste material must be disposed of in compliance with the local guidelines on handling of waste of human-derived material.

OTHER SPECIAL WARNING(S), IF NECESSARY

SAVE THIS DOCUMENT AND PREPARE TO HAVE IT AVAILABLE AT THE TIME OF INFUSION
For autologous use only.
Do Not irradiate.
Do Not Use a Leukodepletion Filter.
Read the package leaflet before use.

I hereby certify that the above information is authentic and accurate. This batch of product has been manufactured, including packaging/labelling and quality control at the above-mentioned site(s) in full compliance with the GMP requirements of the local Regulatory Authority and with the specifications in the Marketing Authorization of the importing country. The batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP.	*Check applicable box* ☐ **Release without Exception** ☐ **Release with Exception**
Completed By/Date:	***Authorized by QA Batch Release Designee/Date:***

*****END OF DOCUMENT*****