



Resolve Designs

PP06, Lot 1284, Certificate of Conformance

RevA

Date:	Aug 13, 2024
RD Part Number:	PP06
Description of Part:	RxCrush® Pill Pouch, 3"x5", 50ml, ENFit®
RD SKUs:	PP06-50, PP06-1000, PP06-4000
Lot #, Date of Mfr:	1284, 2024.05.29
UoM:	50 ea/pack, 20 packs/box (1000 ea), 4 boxes/case (4000 ea), 15 cases/pallet (60000 ea)
Shelf Life:	NA, no expiration date
Manufacturer:	Hopeck, China
Material:	PE, PA, PET, HDPE
Material Supplier:	Hopeck, China
Volume:	60 ml
Item Size (1 ea), Weight:	12.7 x 7.6 x 1.3 cm, 4.2 g
Pack Size (50 ea), Weight:	28 x 18 x 5 cm, 0.2 kg
Box Size (1000 ea), Weight:	38 x 28 x 27 cm, 3.5 kg
Case Size (4000 ea), Weight:	61 x 39 x 56 cm, 14.5 kg
Pallet Size (720000 ea), Weight:	120 x 100 x 183 cm, 218 kg
Evaporation Test:	Loss of water at room temp: 0.011 ml/day, Std Err: 12.2%
Burst Test:	Pouch burst pressure: 4.3 psi, Std Err: 23%
RD FDA Registration #:	Resolve Designs, 3013083631
FDA Classification:	KYX, Dispenser Liquid Medication, Class 1 https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfr/rl.cfm?lid=508352&lpcd=KYX
CE Registration:	Class I, EUDAMED Actor ID: US-MF-000017382 https://webgate.ec.europa.eu/eudamed/secure#/devices/search/view/6603a511-96da-42c1-96b9-cfd2d2dcbf59
EU REACH 1907/2006:	Based on our knowledge, including information from third parties, the article does not contain Substances of Very High Concern (SVHC) above 0.1% by weight.
EU MDR 2017/745, Section 10.4:	Based on our knowledge, including information from third parties, the article does not contain prohibited materials.
RoHS 2015/863/EU Annex II:	Based on our knowledge, including information from third parties, the article does not contain Substances of Very High Concern (SVHC) above 0.1% by weight.
California Prop 65:	Article does not contain materials on the California Proposition 65 list of prohibited substances.
Standards Compliance:	ISO 80369-3
We hereby certify that the materials used in the production of the above items will not be changed without prior notification to our customers.	

We hereby certify that the aforementioned part has been inspected and released by our Quality department.



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