



Resolve Designs

PP11, Lot 1305, Certificate of Conformance

RevA

Date:	Aug 13, 2024
RD Part Number:	PP11
Description of Part:	RxCrush® Sealed Tear-off Pill Pouch, 3"x7"
RD SKUs:	PP11-50, PP11-1000, PP11-4000
Lot #, Date of Mfr:	1305, 2024.09.30
UoM:	50 ea/pack, 20 packs/box (1000 ea), 4 boxes/case (4000 ea)
Shelf Life:	NA, no expiration date
Manufacturer:	Plastmoroz, Poland
Material:	PET12, PE90
Material Supplier:	Plastmoroz, Poland
Item Size (1 ea), Weight:	17.8 x 7.6 x 0.3 cm, 1.8 g
Pack Size (50 ea), Weight:	17.8 x 12.7 x 1.3 cm, 0.09 kg
Box Size (1000 ea), Weight:	40 x 25 x 13 cm, 1.8 kg
Case Size (4000 ea), Weight:	40.5 x 51 x 28 cm, 7 kg
Pallet Size, Weight:	unknown
RD FDA Registration #:	Resolve Designs, 3013083631
FDA Classification:	KYX, Dispenser Liquid Medication, Class 1 https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfrl/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/8a3fbca9-4bf7-46ef-8fb7-72aec95958c6
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.

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.

Aaron Collett
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