

Certificate of Conformance

Date:	Oct 31, 2022
RD Part Number:	PP08
Description of Part:	RxCrush Pediatric Pill Crusher Pouch with Locking ENFit
RD SKUs:	PP08, PP08-50, PP08-5
Lot #, Date of Mfr:	1127, 10/31/2022
UoM:	50 ea/pack, 1000 ea/box, 4000 ea/case
Shelf Life:	NA
Manufacturer:	Hopeck, China
Material:	PE, PA, PET, HDPE
Material Supplier:	China
Size:	11 x 5 x 1.2 cm
Weight:	2.9 g per pouch
Volume:	30 ml
RD FDA Registration #:	Resolve Designs, 3013083631
FDA Classification:	KYX, Dispenser-Liquid Medication, Class 1
CE Registered:	Yes
EUDAMED Actor ID:	US-MF-000017382
Evaporation Test:	Loss of water at room temp: 0.89 ml/day, Std Err: 17.6%
Burst Test:	Pouch burst pressure: 21.6 psi, Std Err: 5.3%
EU REACH 1907/2006:	Based on our knowledge, including information from third parties, 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, article does not contain prohibited materials.
RoHS 2015/863/EU Annex II:	Based on our knowledge, including information from third parties, 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.



Aaron Collett
Quality Director
Resolve Designs