

Certificate of Conformance

Date: 3/26/2025
Part Name: RxCrush® Pill Pouch - 2"x3" - 30ml - Sealed
RD Part Number: PP08
Description of Part: Rx Crush Pill Pouch with locking ENFit®, ISO 80369-3 compliant.
RD SKUs: PP08-5, PP08-50, PP08-1000, PP08-4000, PP08-72000
UoMs: 5/Sample, 50/Pack, 1000/Box, 4000/Case, 72000/Pallet
UoM Packaging Contents: 5 Pieces, 50 Pieces, 20 Packs of 50 ea, 4 Boxes of 1000 ea, 18 Cases of 4000 ea
UoM Dims LxWxH (cm): PP08-5: 12.7 x 7.6 x 0.5, PP08-50: 27.9 x 17.8 x 5.1, PP08-1000: 38.1 x 27.9 x 26.7, PP08-4000: 61 x 39.4 x 55.9, PP08-72000: 121.9 x 101.6 x 203.2
UoM Weight (g): PP08-5: 16, PP08-50: 159, PP08-1000: 3175, PP08-4000: 12701, PP08-72000: 228610
GTINS: 10850006611192, 00850006611195, 30850006611196, 50850006611190, 70850006611194
Lot: 1410
Expiration Date: 3/26/2030
Material: Pouch: PE, PA, PET
Zip: PE
Nozzle: PE

Made In: China
HTS: 3926.90.9989
NMFC: 47550
EMDN: A080199
GMDN: 15750

FDA Establishment #, FDA Listing #, Product Code, Classification: 3013083631, D276971, KYX, Class 1

EU/CE Actor ID, Basic UDI-DI, Class: US-MF-000017382, 0850006611PP8C, Class I

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.



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