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Device Composition Declaration

To Whom It May Concern

Device Name: ChitoGauze XR PRO 3" x 4yds (SafeGuard branded) Part Number 1089

ChitoGauze XR PRO is a rayon / polyester non-woven medical grade gauze coated with chitosan. The chitosan sourced from North Atlantic *Pandalus borealis* shrimp.

Per ISO 22442-1:2020 "Animal" is defined as "vertebrate or invertebrate [including amphibian, arthropod (e.g. <u>crustacean</u>), bird coral, fish, reptile, mollusc and mammal] excluding humans (*Homo sapiens*).

"Derivative" is defined as "substance obtained from an animal material which is involved directly in the manufacturing process of the medical device or is part of the final medical device e.g. Hyaluronic acid, collagen, gelatine, monoclonal antibodies, chitosan and albumin

Therefore, ChitoGauze XR PRO is manufactured utilising tissues of animal origin, or their derivatives, which are non-viable or non-viable. rendered

The composition of the device is as follows:

Chemical and Common Name	CAS#	Percent
Gauze Substance		
Polyester	25038-59-9	50% - 85%
Rayon	61788-77-0	15 – 50%
Micropake Yarn (XR Product)		
Polypropylene Yarn filled w/ Barium Sulphate	N/A	< 5%
Active Mixture		
Chitosan	9012-76-4	< 10%
Glacial Acetic Acid	64-19-7	< 5%

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Date