

**Product name:** Empty Gelatin EZEEFIT Capsules

**Stock code:** 3094, 3095

**BSE/TSE:** Considering the below conditions, as well as the present scientific knowledge about Bovine Spongiform Encephalopathy (BSE) and Transmissible Spongiform Encephalopathy (TSE), the US and European experts from respectively the US Food and Drug Administration and the European Food Safety Authority have declared bovine gelatin and bovine collagen peptides safe end-products regarding BSE/TSE risk.

The manufacturer ensures that bovine gelatin, used for manufacturing of “Hard Gelatin Capsule Shells” conforms to Bovine Spongiform Encephalopathy (BSE) and Transmissible Spongiform Encephalopathy (TSE) regulations as applicable to the country of use:

1. Regulation (EC) No 999/2001 & amendment thereof
2. Regulation (EC) No 853/2004
3. USFDA Sept 1997, Guidance to Industry for the sourcing & processing of gelatin to reduce the potential risk posed by BSE in FDA regulated products.
4. USFDA 21 CFR parts 189,589,700 pertaining to prohibited cattle materials in human food, drugs & cosmetic & animal feeds.
5. USFDA 9 CFR Part 94.23 Importation of gelatin from bovines
6. Commission directive 2003/63/EC and Ph. Eur -1483 evidenced by the **Certificate of Suitability**. The gelatin corresponding to one or more of the following CEP is used SR.No Gelatin Vendors Cep Numbers: R1-CEP 2003-172; R1-CEP 2001-332; R1-CEP 2002-115; R1-CEP 2006-086.

**Vega/Vegetarian:** Empty Gelatin capsules do not comply with a vegan or vegetarian diet.

**GMO:** Empty Gelatin capsules are GMO free and no GMO derived components involved.

**Allergen:** The following items are not used in the manufacturing process of the product, and although manufacturer does not specifically assay for the presence of the items below, however it is unlikely that any traces of these items are present in the starting materials or in the end product.

<input checked="" type="checkbox"/> Cereals containing gluten and products thereof
<input checked="" type="checkbox"/> Corn and products thereof
<input checked="" type="checkbox"/> Celery and products thereof
<input checked="" type="checkbox"/> Soybeans and products thereof
<input checked="" type="checkbox"/> Eggs and products thereof
<input checked="" type="checkbox"/> Dairy Products (Milk, Lactose, Caseinates, Whey)
<input checked="" type="checkbox"/> Peanuts and products thereof
<input checked="" type="checkbox"/> Tree nuts (oils) or derivatives
<input checked="" type="checkbox"/> Mustard and products thereof
<input checked="" type="checkbox"/> Sesame Oil
<input checked="" type="checkbox"/> Sunflower Oil
<input checked="" type="checkbox"/> Sulfites >10ppm
<input checked="" type="checkbox"/> Artificial Colours and Flavours
<input type="checkbox"/> Beef/Chicken/Pork/Fish derivatives
<input checked="" type="checkbox"/> Preservatives

This statement is provided for **informational purposes** only, as instructed to Medisca by the manufacturer, and is not meant to be a guarantee of absence of the above stated allergens.

Salutations

**The MEDISCA Team**

Version: 01

Issued Date: 05/31/2021

Supersedes Date: Not applicable