



**MANUFACTURER'S DECLARATION  
TO WHOM IT MAY CONCERN  
CERTIFIES**

1) That the components (raw materials and products) of bovine origin contained in commercialized products come from healthy and Transmissible Spongiform Encephalopathy (TSE)-free animals originating from TSE-free countries (New Zealand and/or Australia), duly documented and certified by the health authorities in the country of origin and in the country of manufacture.

In any case, our plant ("Reactivos para Diagnóstico, SL") manufacturing process includes a thermal treatment of  $\geq 100^{\circ}\text{C}$  for a minimum of 15 minutes and a spray-drying step with instantaneous heating at  $180\text{-}200^{\circ}\text{C}$ .

2) That all those suppliers that provide us with raw material that may be affected by TSE have the Certificate of Suitability (CEP) alluded to in the General Text (5.2.8) and in the General Monograph of the European Pharmacopoeia concerning TSE risk assessment. According to the EDQM, "Reactivos para Diagnóstico SL", does not require a Certificate of Suitability for products containing bovine/ruminant components since all current "Reactivos para Diagnóstico SL" suppliers of raw materials of this nature comply with the TSE legislation as they possess valid and appropriate certification and therefore the TSE risk has been eliminated prior to the material reaching "Reactivos para Diagnóstico SL" plant.

Therefore, to the best of our knowledge and belief, microbiology products do not pose any risk to users with regard to the TSE agent at this time.

3) That, if the product is enzymatically processed, the enzyme preparation comes from a vegetal source or from healthy animals other than bovine species, free from foot-and-mouth disease, and other controlled infectious diseases.

"Reactivos para Diagnóstico, SL" for microbiology products has all the relevant documentation for each of its production batches as is stated by "Reactivos para Diagnóstico SL" UNI EN ISO 9001:2008 (Certificate Registration N<sup>o</sup> 39 00 0931111) and UNI EN ISO 13485:2004 (Certificate Registration N<sup>o</sup> 39 05 0931111)



This certification covers the following raw materials or components, and all microbiology products that contain them:

Bile Art. No. 07-039; Bile Salts No 3 Art. No. 07-525; Beef Extract Art. No. 07-515; Brain Extract Art. No. 07-076; Skimmed Milk Art. No. 06-019; Casein Pancreatic Peptone Art. No. 07-154; Casein Acid Hydrolysate Art. No. 07-151; Casein Trypsic Peptone (Tryptone) Art. No. 07-119; Gelatine Pancreatic Peptone Art. No. 07-153; Heart Extract Art. No. 07-077; Lactalbumin Art. No. 07-455; Meat Extract Art. No. 07-075; Meat Peptone Art. No. 07-152; Peptone from Casein Art. No. 07-489; Proteose-peptone # 3 Art. No. 07-625 and Tryptose Art. No. 07-197.

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