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IVD Classification

Fannin L.I.P. wishes to advise its customers that the IVD Classification will be removed from the products listed below as, after review it has been determined that they are not a medical device as per the definition listed in the IVD Directive.

IVD Directive 98/79/EC 1998 on *in vitro* medical devices Article 1

in vitro diagnostic medical device means any medical device which, intended by the manufacturer to be used *in vitro* for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information:

- concerning a physiological or pathological state, or
- concerning a congenital abnormality, or
- to determine the safety & compatibility with potential recipients, or
- to monitor therapeutic measures

Products for general laboratory use are not *in vitro* diagnostic medical devices unless such products, in view of their characteristic, are specially intended by their manufacturer to be used for *in vitro* diagnostic examination.

Fannin L.I.P. can confirm that these products will continue to be manufactured under the same conditions and QC testing will remain unchanged.

W11223 Sabouraud Dextrose Agar (Harmonised) 90mm Irradiated Triple Wrap
W11226 Sabouraud Dextrose Agar 40ml
W11234 S.D.A. (Harmonised) 55mm Irradiated Double Wrap
W11235 Sabouraud Dextrose Agar 90mm
W11238 Sabouraud Dextrose Agar (Harmonised) 90mm Irradiated Double Wrap
W11239 S.D.A.+ Chloramphenicol + Actidione
W11422 S.D.A. (Harmonised) 55mm Irradiated Plastic Triple Wrap
W11458 S.D.A. & Chloramphenicol 55mm Irradiated Double Wrap
W11513 McConkey Agar (Harmonised Formula)
W11525 Mannitol Salt Agar (Harmonised Formula)
W14035 Peptone Water
W14047 Peptone Water 0.1% 4ml
W14048 Peptone Water 10ml
W14088 Sabouraud Dextrose Agar (Universal)
W14135 Sabouraud Dextrose AGAR (Harmonised) 500ml PP Bottle
W14236 Peptone Water +Lecithin 0.5% + TWEEN 4.0% 9ml
W14296 Peptone Water 100ml PET Bottle
W14310 Peptone Water + 4% Tween 80 1L PP Bottle
W14311 Peptone 0.1% + Tween 0.1% 900ml PP Bottle
W14330 Peptone WATER 9ml
W14338 Peptone WATER 0.1% 400ml PET Bottle
W14340 Sabouraud Dextrose Agar (Harmonised) 100ml PP Bottle
W14354 Sabouraud Dextrose Agar (Harmonised) 300ml PP Bottle
W14360 Sabouraud Dextrose Agar (Harmonised) 200ml PP Bottle
W14024 TB Buffer Indicator
W14097 TB Buffer Solution (TB20)
W14111 TB Buffer Solution 25ml (TB25)
W14359 TB Buffer 20ml
W14370 TB Buffer Solution 25ml
W14401 TB Buffer 14ml

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