

Boric Acid for bacteriostasis.

Porter and Brodie¹ tried various transport methods and found that boric acid provided the most reliable method of maintaining microorganisms at concentrations close to their original in transit by various means and over several days. Originally a concentration of 2% was used, but it was later shown that some organisms could be affected by this level². MW& E's Boricon[®] M40 contains 200mg boric acid fine powder (fast dissolving) to give a 1% concentration for a 20ml fill. This prevents any significant bacterial growth without adversely affecting fastidious organisms. The fine powder dissolves readily ensuring no interference with cell or particle counting.

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NCCLS M40A³ requires challenge testing of preservative containing containers with relevant uropathogens for typical transit and holding periods. Plate counts are to remain within 1 log₁₀ of the initial organism concentration. This is included in MW & E's protocol for Boricon[™] M40.

- **NCCLS M40A** is a new standard which allows manufacturers to specify the performance which can be expected from a transport device, and give users a set of criteria they can use to accurately evaluate transport devices.
- The EU's **In Vitro Diagnostic Medical Devices Directive** (1998) ensures that the product in itself presents no danger to the patient, either by being harmful in use, or by yielding false information about the patients specimen.
- **ISO 9001:2000 & ISO 13485:2003** Quality Assurance for the design and manufacture of devices you can rely on.

Notified Body for the European Union In Vitro Diagnostic Directive 98/79/EC in July 2000.

The In-vitro Diagnostic Medical Devices Directive was published in the Official Journal on 27th October 1999 as Directive number: 98/79/EC. The UK government had until the 7th of December 1999 to transpose the Directive into UK law and CE marking against the Directive will be permitted from June 2000

The *In Vitro* Diagnostic Medical Devices Directive (98/79/EC) was formally adopted at the General Affairs Council of Ministers on 5th October 1998 and was published in the Official Journal of European Communities on 7th December 1998 (ref L331/1).

References

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- *In Vitro* Diagnostic Medical Devices Directive (98/79/EC), 1998, Official Journal of European Communities, L331/1