



## Declaration of Conformity

In accordance with ISO/IEC Guide 22.

|   |   |
|---|---|
| <b>Name of Device:</b>  | <b>Kova®-Trol; Kova® Liqua-Trol</b>   |
| <b>Product Code:</b>  | 87100, 87110, 87112, 87116, 87122, 87123, 87128, 87130, 87176, 87177, 87325, 87326, 87327, 87328, 87329, 87331, 87332, 87333, 87334<br>87100E, 87112E, 87116E, 87122E, 87123E, 87128E, 87130E, 87176E, 87177E, 87325E, 87326E, 87327E, 87329E, 87331E, 87332E, 87333E, 87334E, 37036<br>Routine urinalysis controls |
| <b>Manufacturer:</b>  | <b>Hycor Biomedical</b>   |
| <b>Address:</b>   | 7272 Chapman Avenue<br>Garden Grove, CA 92841<br>USA  |
| <b>Authorized Rep</b>   | Hycor Biomedical Ltd<br>Pentlands Science Park, Bush Loan<br>Penicuik, Midlothian, Scotland, EH26 OPL   |
| <p>The device described above is in conformity with Directive 98/79/EC of the European Parliament and of the Council of 27<sup>th</sup> October 1998 on In Vitro Diagnostic Medical Devices, published in the Official Journal on 7<sup>th</sup> December 1998. The devices are classed as 'General IVDs' and as such this declaration of conformity is self-certified.</p> |   |
| <b>Additional information</b>   |   |
| <b>Date of issue:</b>   | 17 November 2008  |
| <b>Place of issue:</b>  | Hycor Biomedical  |
| <b>Signed:</b>  |    |
| <b>Name:</b>  | Randy A. Wilson   |
| <b>Function:</b>  | Director, World Wide Regulatory Affairs   |

## Declaration of Conformity

In accordance with ISO/IEC Guide 22.

|   |  |
|---|--|
| <b>Name of Device:</b>  | <b>Kova® System Plastics</b>   |
| <b>Product Code:</b>  | 87100E, 87118E, 87135E, 87136E, 87137E, 87138E, 87139E,<br>87141E, 87144E, 87144F, 87146E, 87153E, 87154E, 87155E,<br>87156E, 87157E, 87159E, 87162E<br><b>Disposable plastic laboratory equipment</b> |
| <b>Manufacturer:</b>  | <b>Hycor Biomedical</b>  |
| <b>Address:</b>   | 7272 Chapman Avenue<br>Garden Grove, CA 92841<br>USA   |
| <b>Authorized Rep</b>   | <b>Hycor Biomedical Ltd</b>  |
|   | <b>Pentlands Science Park, Bush Loan</b>   |
|   | <b>Penicuik, Midlothian, Scotland, EH26 OPL</b>  |
| <p>The device described above is in conformity with Directive 98/79/EC of the European Parliament and of the Council of 27<sup>th</sup> October 1998 on In Vitro Diagnostic Medical Devices, published in the Official Journal on 7<sup>th</sup> December 1998. The devices are classed as 'General IVDs' and as such this declaration of conformity is self-certified.</p> |  |
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| <b>Function:</b>  | Director, World Wide Regulatory Affairs  |