



FOR IMMEDIATE RELEASE

## NuSep achieves Therapeutic Goods Administration (TGA) accreditation for Diagnostics

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**Sydney, Australia 12<sup>th</sup> November 2012** – NuSep (ASX:NSP) wishes to advise the market that it has been accredited by the Australia Therapeutic Goods Administration (TGA) for the manufacture of *in-vitro* diagnostics medical devices (IVDs) used in the field of coagulation. NuSep is one of the first IVD manufacturers in Australia to have achieved this accreditation under the recently introduced requirement for ISO 13485 compliance.

Mr Prakash Patel, Managing Director of NuSep Australia added that “the TGA accreditation will allow NuSep to expand its *in-vitro* diagnostics product range offering which will allow NuSep to capture the highly profitable \$5m diagnostic market.”

NuSep will now seek registration of its *in-vitro* diagnostics products with the European Union (EU) to allow the sale of these products in the EU region. EU registration is expected to be completed in early 2013 with NuSep currently in discussions with European distributors for the sale of its coagulation products in the EU.

ISO 13485 accreditation requires a stringent audit of the company’s quality and manufacturing systems by the TGA. This certification impacts on all of NuSep’s quality and manufacturing systems within the Company. This certification will help NuSep which is now preparing the membrane manufacturing process to supply PRIME Biologics with cartridges to manufacture therapeutic plasma products and SpermGen with IVF cartridges.

**\*\*ENDS\*\***

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### About NuSep

NuSep (ASX: NSP) is a publicly listed life sciences company that sells products into the global BioSeparations market. NuSep recently acquired BioInquire which developed the ProteolQ software enabling NuSep to offer a total Proteomics solution from **Fraction to Function**. The company has offices in both Sydney Australia and Atlanta, USA.

With a 30 year heritage in biological separations, NuSep has forged a world class reputation for its innovative yet simple biological separation techniques including the world’s first IVF sperm separation device. In short NuSep has redefined the BioSeparations market through innovation and simplification.

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NuSep's world renowned research team has developed an extensive portfolio of patented products. In all, NuSep currently manufactures, distributes and sells 55 products to customers in the USA, Europe, Asia and Australia.

NuSep Products:

-  **Gels** – NuSep manufactures and sells precast gels including the innovative nUView Gels, which can be visualised 2 minutes after use.
-  **Separation Instruments** – NuSep has developed two unique biological separation instruments. The ProteomeSep was released in 2009 and can separate biological samples into 8 fractions for use in the proteomic market. The SpermSep separates sperm for fertility treatments such as IVF.
-  **Proteomics Software** – NuSep offers the unique ProteoIQ software for the analysis of complex mass spec samples. This software is also designed to identify bio markers.
-  **Biological Products** – NuSep supplies research grade biological products manufactured using its unique separation technologies. These products include human IgG and Albumin.

For more information about NuSep please visit the company's website [www.NuSep.com](http://www.NuSep.com)

#### **About PrIME Biologics Pte Ltd**

PrIME Biologics is a Singapore based biotech company that has developed a disposable therapeutic plasma manufacturing process based on NuSep's PrIME Technology. NuSep has a 90% shareholding in PrIME Biologics. PrIME Biologics process is based on the **P**reparative **I**solation by **M**embrane **E**lectrophoresis (PrIME) technology developed by NuSep. PrIME provides disposable modular processing that is 'electronically' driven membrane fractionation.

The PrIME process increases product yields to over 90% relative to the existing process 50% while increasing product safety. The PrIME has been shown to remove virus, bacteria, endotoxins and prions which cause 'Mad Cow Disease'. Further, PrIME Biologics process can produce multiple plasma products in hours compared to days, which is required by the current manufacturers.

The initial application for the PrIME process will be the *Currently Unprocessable Plasma* which represents approximately 50% of all the plasma collected in many Asian countries.