



CERTIFICATE

The Certification Body
of TÜV SÜD Management Service GmbH
Trading as TÜV SÜD South Asia Private Limited

certifies that

BIO PLUS LIFE SCIENCES PRIVATE LIMITED

PHARMED GARDENS WHITEFIELD ROAD,
BANGALORE- 560 048

has established and applies
a Food Safety Management System for

Manufacture of Food Supplements in Form of Tablets, Capsules & Powders

An audit was performed, Report No. 70072209

Proof has been furnished that the requirements
according to

ISO 22000: 2005

are fulfilled. The certificate is valid until **2010-12-19**

Certificate Registration No. **1251022763 TMS**



Munich, 2007-12-21



TGA-ZM-07-92



Management Service

CERTIFICATE

The Certification Body
of TÜV SÜD Management Service GmbH
Trading as TÜV SÜD South Asia Private Limited
certifies that

BIO PLUS LIFE SCIENCES (P) LTD.
PHARMED GARDENS,
WHITEFIELD ROAD,
BANGALORE - 560 048, INDIA

has established and applies
an Environmental Management System for

**Design and Manufacture of
Pharmaceutical and Nutritional / Dietary
Supplements like Tablets, Capsules and Powder**

An audit was performed, Report No. 70072209
Proof has been furnished that the requirements
according to

ISO 14001:2004

are fulfilled. The certificate is valid until **2012-09-16**
Certificate Registration No. **12 104 22763 TMS**



M. Nagel

Munich, 2009-09-17



EMS-TGA-ZM-07-92



CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

Issued following an inspection in accordance with Art. 111(5) of Directive 2001/83/EC.

The competent authority of *Denmark* confirms the following:

The manufacturer **BioPlus Life Sciences Private Ltd**

Site address: **Pharmed Gardens, Whitefield Road, Bangalore 560048, India**

has been inspected in connection with marketing authorisation(s) listing manufacturers located outside of the European Economic Area in accordance with Art. 111(4) of Directive 2001/83/EC/Art. 80(4) transposed in the following national legislation: (*Consolidated*) *Medicinal Products Act, 2005, as amended*.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **May 20-22, 2008**, it is considered that it complies with the Good Manufacturing Practice requirements referred to in The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC2.

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection, after which time the issuing authority should be consulted.

The authenticity of this certificate may be verified with the issuing authority.



Part 2

Human Medicinal Products

1 MANUFACTURING OPERATIONS

- Authorised manufacturing operations include total and partial manufacturing (including various processes of dividing up, packaging or presentation), batch release and certification, storage and distribution of specified dosage forms unless informed to the contrary.
- Quality control testing and/or release and batch certification activities without manufacturing operations are specified under the relevant items.
- If the company is engaged in manufacture of products with special requirements e.g. radiopharmaceuticals or products containing penicillin, cytotoxics, cephalosporins, substances with hormonal activity or other potentially hazardous active ingredients this is stated under the relevant product type and dosage form.

1.2 Non-sterile products

1.2.1 Non-sterile products
1.2.1.13 Tablets

Any restrictions or clarifying remarks related to the scope of this certificate: *Dolenio (Glucosamine)*

Date: *September 19, 2008*

Name and signature of the authorised person
of the competent authority of Denmark:


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Ole Milling, Medicines Inspector

The Danish Medicines Agency

E-mail: dkma@dkma.dk

Fax: +45 4488 9195