



Certificate Number  
294 CE

Initial Certification Date  
13 October 1998

Certificate Issue Date  
02 June 2008

Certificate Expiry Date  
12 October 2013

*The certification is subject to the organization maintaining their system in compliance with the regulations stated in this certificate, allowing regular assessments and following the contracted requirements of the Notified Body.*

*This Certificate is for the exclusive use of AMTAC's client and is provided pursuant to the agreement between AMTAC and its Client. AMTAC's responsibility and liability are limited to the terms and conditions of the agreement. AMTAC assumes no liability to any party, other than to the Client in accordance with the agreement, for any loss, expense or damage occasioned by the use of this Certificate. Only the Client is authorized to permit copying or distribution of this Certificate. Any use of the AMTAC name or one of its marks for the sale or advertisement of the tested material, product or service must first be approved in writing by AMTAC.*

*AMTAC Certification Services Limited is a Notified Body according to Directive 93/42/EEC for medical devices, with identification number 0473.*

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# EC Certificate

**FULL QUALITY ASSURANCE SYSTEM**

**Directive 93/42/EEC for Medical Devices, Annex II (3)**

We hereby declare that an examination of the under mentioned full quality assurance system has been carried out following the requirements of the UK national legislation to which the undersigned is subjected, transposing Annex II (with the exemption of section 4) of the Directive 93/42/EEC on medical devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive, and the result entitles the organization to use the CE 0473 marking on those products listed below.

## Organization:

**BIONICHE PHARMA GROUP LTD**  
**trading as BIONICHE TEORANTA**

Situated at:

Coill Rua, Inverin, County Galway, Republic of Ireland

And at:

Unit 6, Casla Industrial Estate, Casla, County Galway,  
Republic of Ireland

Suplasyn<sup>®</sup> sterile sodium hyaluronate solution  
Suplasyn md<sup>®</sup> sterile sodium hyaluronate solution  
Cystistat<sup>®</sup> sterile hyaluronate solution

Authorized Signatory

R. NASH

AMTAC Certification Services Limited, Milton Keynes, UK

APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. Country Ireland

This public document

2. has been signed by *Kevin P. Geraghty*

3. acting in the capacity of *Notary Public*

4. bears the seal/stamp of.....

Certified

5. at Dublin..... 6. the *17/6/2008*

7. by the Department of Foreign Affairs

8. No. *30490/08*

9. Seal/Stamp:

10. Signature:

*Kevin P. Geraghty*



I, KEVIN P. GERAGHTY Notary  
Public for the County and City of  
Galway HEREBY CERTIFY that this is a true  
and faithful copy of the original document  
now to me produced fair and uncanceled  
after which careful examination I attest.

*Kevin P. Geraghty* 12/6/08

Kevin P. Geraghty  
1 Rosemary Avenue  
Eyre Square, Galway, Ireland.  
Notary Public  
Commissioned for Life