

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

No. CE 72373
Issued To: **Adelphi Tubes Ltd**
Olympus House
Mill Green Road
Haywards Heath
RH16 1XQ
United Kingdom

In respect of:

Those aspects relating to securing and maintaining sterility in the manufacture of sterile nitrogen-filled vials.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):



Frank Lee, EMEA Compliance & Risk Director

First Issued: **04 May 2006**

Date: **17 June 2016**

Expiry Date: **03 May 2021**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

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List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

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Subcontractor:

Service(s) supplied

BAG Health Care GmbH
Amtsgerichtsstraße 1-5
35423 Lich
Germany

Aseptic Processing

GIPHARMA S.r.l.
Strada Crescentino snc
Saluggia
13040
Italy

Aseptic Processing

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EC Certificate - Production Quality Assurance Certificate History

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Date	Reference Number	Action
04 May 2006		First issue.
29 June 2010		Addition of significant subcontractor GIPharma S.r.l. for aseptic sterilization and name change of BAG Biologische Analysensystem GmbH to BAG Health Care GmbH.
19 April 2011	7666428	Certificate renewal.
17 June 2016	8546308	Certificate renewal.

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