By Royal Charter

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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EC Certificate - Production Quality Assurance

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

List of Significant Subcontractors

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

Certificate No:	**CE 72373**
Date:	**17 June 2016**
Issued To:	**Adelphi Tubes Ltd** **Olympus House** **Mill Green Road** **Haywards Heath** **RH16 1XQ** **United Kingdom**

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

Certificate No: **CE 72373**

Date: **17 June 2016**

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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 Analyscnsystem Gmbh to BAG Health Care GmbH.
19 April 2011	7666428	Certificate renewal.
17 June 2016	8546308	Certificate renewal.

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