

# 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 2797):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2006-05-04**

Date: **2020-02-10**

Expiry Date: **2024-05-26**

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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.

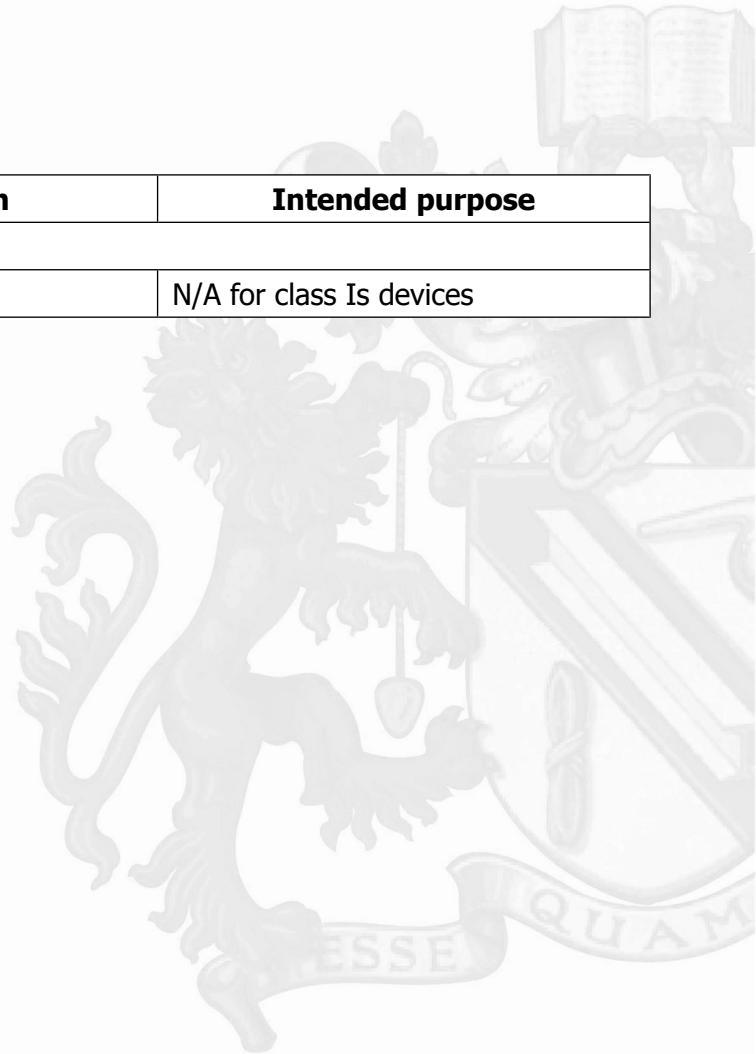
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## Supplementary Information to CE 72373

Issued To:

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NBOG code(s)	Device Description	Intended purpose
Class Is		
MDS7006	Sterile nitrogen-filled vials	N/A for class Is devices



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

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

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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  
D-35423 Lich  
Germany

**Aseptic Processing**

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# EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 72373**  
 Date: **2020-02-10**  
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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.
05 March 2019	7780128	Traceable to NB 0086.
Current	3060498	Certificate renewal and inclusion of supplementary page to include device information. Removal of Gipharma Srl as significant subcontractor. Administrative correction to subcontractor postcode (BAG Health Care GmbH).