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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 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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Supplementary Information to CE 72373

Issued To:

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

First Issued: **2006-05-04** Date: **2020-02-10** Expiry Date: **2024-05-26**

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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:	**2020-02-10**
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 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**
Issued To: **Adelphi Tubes Ltd**
Olympus House
Mill Green Road
Haywards Heath
RH16 1XQ
United Kingdom

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.
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).

Adelphi (Tubes) Limited
Olympus House
Mill Green Road
Haywards Heath
RH16 1XQ
United Kingdom

5th July 2024

Notified Body Confirmation Letter
Reference: EU2023-607/ 906525

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, **BSI Group The Netherlands B.V.**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **2797** on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Adelphi (Tubes) Limited
Olympus House
Mill Green Road
Haywards Heath
RH16 1XQ
United Kingdom
SRN Number: UK-MF-000042179

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of BSI Group The Netherlands B.V.,

Graeme Tunbridge
Senior Vice President, Medical Devices

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Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Sterile Nitrogen Filled Vials	Class I device placed on the market in sterile condition	N/A	Certificate CE 72373; NB2797

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	Action
2024/07/05	Initial issue