

UKCA Certificate - Production Quality Assurance

Part II of The Medical Devices Regulations 2002, Annex V [as modified by Part 2 of Schedule 2A to The Medical Devices Regulations 2002]

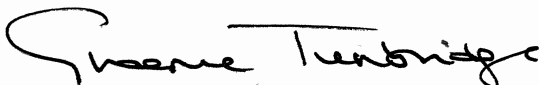
No. UKCA 799066
Issued To: **Adelphi (Tubes) Limited**
Olympus House
Mill Green Road
Haywards Heath
RH16 1XQ
United Kingdom

In respect of:

Those aspects of Annex V relating to securing and maintaining sterility of nitrogen-filled vials.

On the basis of our examination of the quality assurance system under the requirements of Part II of the Medical Devices Regulations 2002, Annex V [as modified by Part II of Schedule 2A to The Medical Devices Regulations 2002]. The quality assurance system meets the requirements of the regulation. For the placing on the market of class IIb and class III products an Annex III certificate (modified as described above) is required.

For and on behalf of BSI, an Approved Body for the above Regulation (Approved Body Number 0086):



Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

First Issued: **2025-01-13**

Date: **2025-01-13**

Expiry Date: **2029-12-04**

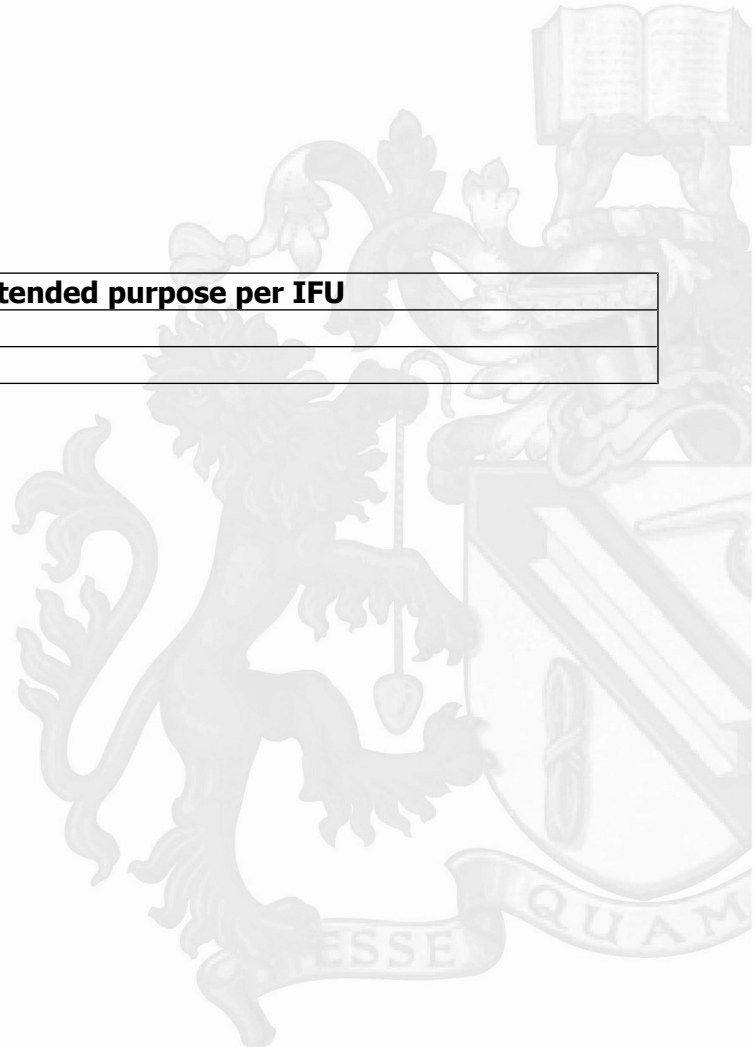
...making excellence a habit.™

UKCA Certificate - Production Quality Assurance

Supplementary Information to UKCA 799066

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

Device Code	Device Name	Intended purpose per IFU
Class Is		
MD 0106	Sterile Nitrogen Filled Vials	---



First Issued: **2025-01-13**

Date: **2025-01-13**

Expiry Date: **2029-12-04**

...making excellence a habit.™

UKCA Certificate - Production Quality Assurance

Certificate History

Certificate No: **UKCA 799066**
Date: **2025-01-13**
Issued To: **Adelphi (Tubes) Limited**
Olympus House
Mill Green Road
Haywards Heath
RH16 1XQ
United Kingdom

Date	Reference Number	Action
Current	30032269	First Issue; Traceable to MDR 799065

...making excellence a habit.™