By Royal Charter

# UKCA Certificate - Full Quality Assurance System

Part II of The Medical Devices Regulations 2002, Annex II excluding Section 4 [as modified by Part 2 of Schedule 2A to The Medical Devices Regulations 2002]

**No.** **UKCA 782007**

Issued To: **iM Med Ltd**
**1 Pembroke Ave**
**Waterbeach**
**Cambridgeshire**
**CB25 9QP**
**United Kingdom**

In respect of:

**Design, manufacture and final inspection of chemical disinfectants for use on invasive medical devices and endoscope clean storage systems**

On the basis of our examination of the quality assurance system under the requirements of Part II of the Medical Devices Regulations 2002, Annex II excluding Section 4 [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 III products an Annex II (modified as described above) Section 4 certificate 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: **2022-11-16** Date: **2025-12-09** Expiry Date: **2027-11-29**

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**Supplementary Information to UKCA 782007**

Issued To:

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**United Kingdom**

| Device code | Device name | Intended purpose per IFU |
|---|---|---|
| **Class IIb** | | |
| MD 0108 | Medical Device Disinfectant (2%, 5% and 15% peracetic acid) | Intended for chemical disinfection of endoscopes using an automated endoscope reprocessor. |
| **Class Is** | | |
| MD 0108 | Endoscope clean storage system | --- |

First Issued: **2022-11-16** Date: **2025-12-09** Expiry Date: **2027-11-29**

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# UKCA Certificate - Full Quality Assurance System Certificate History

Certificate No: **UKCA 782007**
Date: **2025-12-09**
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| Date | Reference Number | Action |
|---|---|---|
| 2022-11-16 | 3806073 | Issued Traceable to CE 667383 |
| 2022-11-23 | 3807671 | Certificate Renewal |
| Current | 30584132 | Scope: Addition of class Is Endoscope clean storage system<br>Device Schedule: Addition of class Is Endoscope clean storage system device group |

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