



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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Validity of this certificate is conditional on the quality system being maintained to the requirements of the regulation as demonstrated through the required surveillance activities of the Approved Body.

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

Approved Body Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes, MK5 8PP, UK. Tel: + 44 845 080 9000 Corporate Contact: BSI Assurance UK Limited, registered in England under number 7805321 at Seventh and Eighth Floors, The Acre, 90 Long Acre, London, WC2E 9RA, UK.





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Supplementary Information to UKCA 782007

Issued To: iM Med Ltd

1 Pembroke Ave Waterbeach Cambridgeshire CB25 9QP 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	(

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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 Device Schedule: Addition of class Is Endoscope clean storage system device group

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