By Royal Charter

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 782009 R000

Manufacturer: iM Med Ltd

Address:
1 Pembroke Avenue
Waterbeach
Cambridgeshire
CB25 9QP
United Kingdom

Single Registration Number: GB-MF-000009796

EU Authorised Representative: Advena Limited

Address:
Tower Business Centre, 2nd Flr.,
Tower Street
Swatar, BKR 4013
Malta

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

First Issue Date: **2024-03-21**

Current Issue Date: **2025-12-04**

Starting Validity Date: **2025-12-04**

Expiry Date: **2029-03-20**

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Device Schedule: Class III and Class IIb devices

Class IIb	Intended purpose
Peracetic acid with hydrogen peroxide for the disinfection of medical devices	Intended for the chemical disinfection of invasive medical devices such as flexible endoscopes and for use in automated endoscope washer disinfectors.

Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Endoscope clean storage system	Class Is
For Class Is devices, the Notified Body conformity assessment is limited to the aspects relating to establishing, securing and maintaining sterile conditions.	

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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
2024-03-21	3806076	Issued
Current	30584131	Supplemented – addition of class Is Endoscope clean storage system device group

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

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