By Royal Charter

EU Quality Management System Certificate

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

MDR 782156 R000

Manufacturer: Allmed Middle East

Address:
2nd Industrial Zone No.:72
6th October City
Giza 12541
Egypt

Single Registration Number: EG-MF-000025747

EU Authorised Representative: Allmed Medical GmbH

Address:
Mittelbacherstr. 18
01896 Pulsnitz
Germany

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: **2024-03-18**

Current Issue Date: **2026-05-14**

Starting Validity Date: **2026-05-14**

Expiry Date: **2029-03-17**

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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.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at Seventh and Eighth Floors, The Acre, 90 Long Acre, London, WC2E 9RA, UK.
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Device Schedule: Class III and Class IIb devices

Class IIb	Intended purpose
Hollow Fiber Hemodialyzer Synthetic membrane UHF < 18 ml/h/mmHg	Hollow Fiber Hemodialyzers are used for adult patients with acute or chronic renal failure. It is intended to be used for hemodialysis treatment.
Hollow Fiber Hemodialyzer Synthetic membrane UHF = 18 - 35 ml/h/mmHg	Hollow Fiber Hemodialyzers are used for adult patients with acute or chronic renal failure. It is intended to be used for hemodialysis treatment.
Hollow Fiber Hemodialyzer Synthetic membrane Steam – UHF > 35 ml/h/mmHg	Hollow Fiber Hemodialyzers are used for adult patients with acute or chronic renal failure. It is intended to be used for hemodialysis treatment and hemodiafiltration treatment.
Hollow Fiber Hemofilter Synthetic membrane UHF < 18 ml/h/mmHg	Hemofilter is intended for CRRT machine-supported use under pressure monitoring in either continuous hemofiltration: CVVH, SCUF, HV CVVH, CVVHDF and CVVHFD
Hollow Fiber Hemofilter Synthetic membrane UHF= 18 - 35 ml/h/mmHg	Hemofilter is intended for CRRT machine-supported use under pressure monitoring in either continuous hemofiltration: CVVH, SCUF, HV CVVH, CVVHDF and CVVHFD
Hollow Fiber Hemofilter Synthetic membrane UHF> 35 ml/h/mmHg	Hemofilter is intended for CRRT machine-supported use under pressure monitoring in either continuous hemofiltration: CVVH, SCUF, HV CVVH, CVVHDF and CVVHFD
Dialysis Concentrate, Basic Solutions, Powder Sodium Bicarbonate Container (Cartridge and Bag)	Bicarbonate cartridges/bags are intended to be used during hemodialysis treatments for Bicarbonate-based hemodialysis solutions. It must always be used together with a acid concentrate.
Dialysis Cleaning Cartridge	Disinfection and decalcification of the fluid path of the hemodialysis machine.

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

Device(s)	Risk Classification
Arterial and Venous Bloodlines	Class IIa
Bacterial and Endotoxin Retention filter	Class IIa

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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
2024-03-18	3808283	Issued
2024-05-22	30181053	Amended – Addition of supplier for Polysulfone hollow fiber membrane for hemodialyzers.
2024-07-26	30227562	Amended – Addition of supplier for Polyethersulfone hollow fiber membrane for hemodialyzers Supplemented – Addition of new device codes (range Vaporia) in the existing range of Polyethersulfone Hollow Fiber Hemodialyzer
2024-10-14	30287719	Amended – Administrative update to align device description with EMDN code for Dialysis Concentrate, Basic Solutions, Powder
Current	30724526	Supplemented – Addition of supplier for Polyethersulfone hollow fiber membrane for hemodialyzer Supplemented – Addition of new devices codes BIOPURE LFX and BIOPURE HFX in the existing range of Hollow Fiber Hemodialyzer polyethersulfone Supplemented – Addition of new device range Hollow Fiber Hemofilter Polysulfone ACUTE HH Supplemented – Addition of new device range Bacterial and Endotoxin Filter Endostop

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