EU Certificate

Quality Management System
REGULATION (EU) 2017/745 on Medical Devices
Annex IX Chapter I, Section 2 and 3 and Chapter III

Registration No.:	HZ 2087599-1
Manufacturer:	BQ Plus Medical Co., Ltd. No. 18, Che Ye Road, Che Dun Town, Songjiang, 201611 Shanghai P.R. China
EUDAMED Single Registration No.:	CN-MF-000010259
Products:	Products of class I, sterile: A030101 - INFUSION CONTROLLERS A030201 - EXTENSIONS A070103 - INFUSION LINES ADAPTERS AND CONNECTORS A070502 - CAPS OR OBTURATORS, PERFORABLE A030103 - ENTERAL FEEDING CONTROLLERS A020108 - ENTERAL FEEDING SYRINGES The scope of certification is limited to the aspects relating to establishing, securing and maintaining sterile conditions Products of class IIa: R030101 - VENTILATION MASKS A030103 - ENTERAL FEEDING CONTROLLERS A030101 - INFUSION CONTROLLERS

The Notified Body hereby declares that the requirements of Annex IX, Chapter I, Section 2 and 3 of the REGULATION (EU) 2017/745 have been met for the listed products. The above named manufacturer has established and applies a quality management system, which is subject to periodic surveillance, defined by Annex IX, Chapter I, Section 3 of the aforementioned regulation. The requirements of Annex IX, Chapter III are fulfilled.
If class III devices or class IIb implantable devices referred to in the second subparagraph of Article 52(4) are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 4.9 is required before placing them on the market.

Report No.:	244518051-200
Effective date:	2025-06-03
Expiry date:	2030-06-02
Issue date:	2025-06-03

Fuxiu Sheng
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

This certificate can be validated on https://www.certipedia.com

TÜV Rheinland LGA Products GmbH is a Notified Body according to REGULATION (EU) 2017/745 concerning medical devices with the identification number 0197.

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
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EU Certificate

Quality Management System
REGULATION (EU) 2017/745 on Medical Devices
Annex IX Chapter I, Section 2 and 3 and Chapter III

Registration No.:	HZ 2087599-1
Manufacturer:	BQ Plus Medical Co., Ltd. No. 18, Che Ye Road, Che Dun Town, Songjiang, 201611 Shanghai P.R. China
EUDAMED Single Registration No.:	CN-MF-000010259
	Products of class I, with measuring function: A020108 - ENTERAL FEEDING SYRINGES A030103 - ENTERAL FEEDING CONTROLLERS A030101 - INFUSION CONTROLLERS The scope of certification is limited to the aspects relating to the conformity of the devices with the metrological requirements
Authorized representative(s):	Prolinx GmbH Brehmstr. 56, 40239, Duesseldorf, Germany

Certificate history		
Revision:	Description:	Issue date:
0	Initial certification	2025-06-03

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