



인정번호(No.) : TRK-BABA-23413

의료기기 제조 및 품질관리 기준 적합인정서 (Certificate of GMP)

■ 업소명/허가번호 (Company name of Applicant / License No.)

(주)메디포스/제 1500 호
MEDIFORCE



■ 업소 소재지 (Company address of Applicant)

서울특별시 송파구 충민로 66L-7132호, 7135호(문정동, 가든파이브라이프)
RM L-7132, 7135 66, Chungmin-ro, Songpa-gu, Seoul, Korea (Munjeong dong, Garden Five Life)

■ 제조소명 (Name of Manufacturer)

제 조 자 : BQ Plus Medical Co., Ltd. / KZBQ(Jiangsu) Medical Co., Ltd.(a)

■ 제조소 소재지 (Address of Manufacturer)

제 조 자 : No 18, Che Ye Road, Che Dun Town, Songjiang, 201611 Shanghai P.R. China / No.12, Gaogang New Zone, Huaigao Town, Huaiyin district, Huai An City, 223300 Jiangsu, P.R. China(a)

■ 품목군 (Category)

붙임참조 (See attached list)

의료기기 제조 및 품질관리기준에 적합함을 인정합니다.

(We hereby certify that the above manufacturer complies with Korea Good Manufacturing Practices of Medical Devices for the product group listed above)

발행일자(Date of Issue) : 2025. 04. 04

유효기간(Date of Expiration) : 2028. 04. 03



티유브이라인란드코리아(주) 대표

TUV Rheinland Korea Ltd.



변경 및 처분 사항 등(Changes and Administrative measures)	
년 월 일(Date)	내 용(Description)
2025-04-04	최초심사

비이식형혈관접속용기구
제조소:KZBQ(Jiangsu) Medical Co., Ltd.
주소:No 18, Che Ye Road, Che Dun Town, Songjiang, 201611 Shanghai P.R. China/No.12, Gaogang New Zone, Huaigao Town, Huaiyin district, Huai An City, 223300 Jiangsu, P.R. China(a)



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인정번호(No.) : TRK-BABA-23413
[붙임1]

순번(NO.)	품목군(Name of Category)	비 고(Remarks)
1	의료용 취관 및 체액 유도관(I) Tube and Catheter for medical use(I)	
2	의약품 주입기(I) Infusion instruments(I)	



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인정번호(No.) : TRK-BABA-23413
[붙임2]

시설물 상세정보

제조사 :
(상호명) BQ Plus Medical Co., Ltd.(제조사 A)
(소재지) No 18, Che Ye Road, Che Dun Town, Songjiang, 201611 Shanghai P.R. China
(상호명) KZBQ(Jiangsu) Medical Co., Ltd.(제조사 B)
(소재지) No.12, Gaogang New Zone, Huaigao Town, Huaiyin district, Huai An City,
223300 Jiangsu, P.R. China

본사와 공장을 제조자 A와 B로 구분하고, 현장조사 대상인 제조자는 B로 작성
(제조자 A는 2024.07.02 GMP 갱신 하였습니다)



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